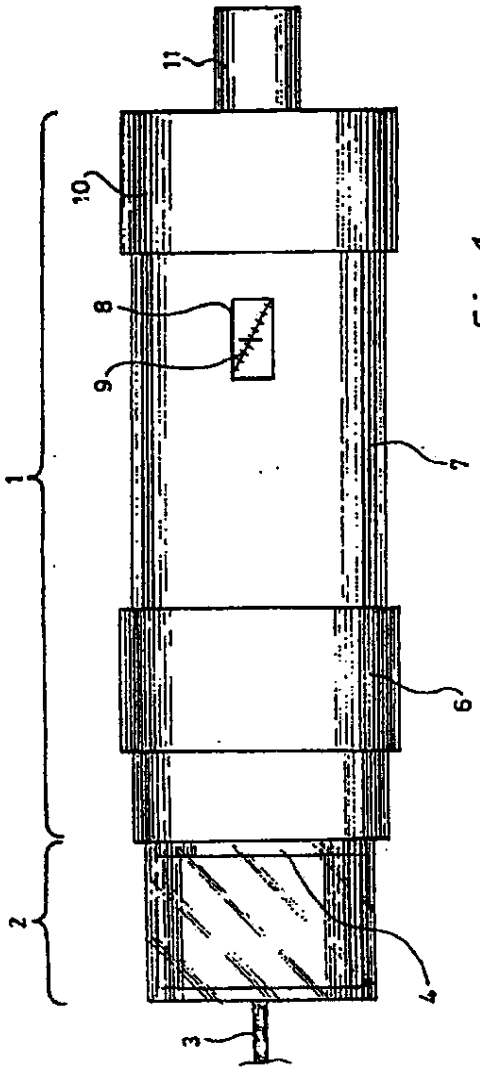
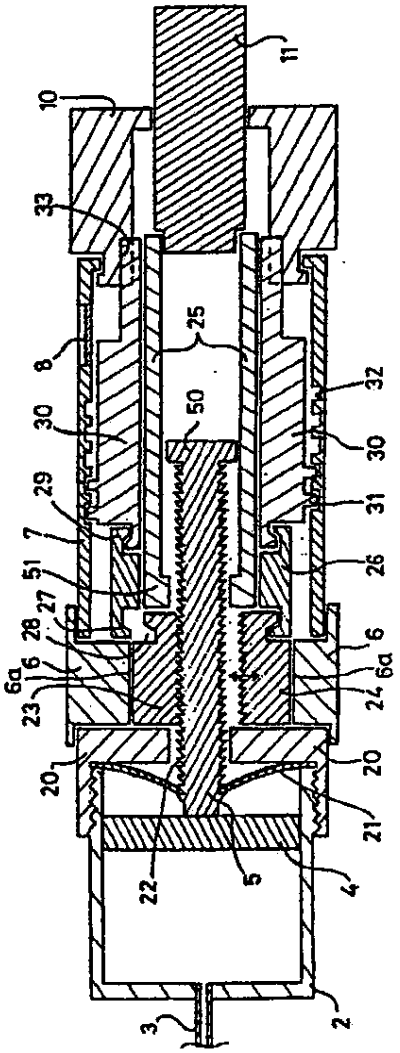


Fig. 1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6a
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6a
23
24
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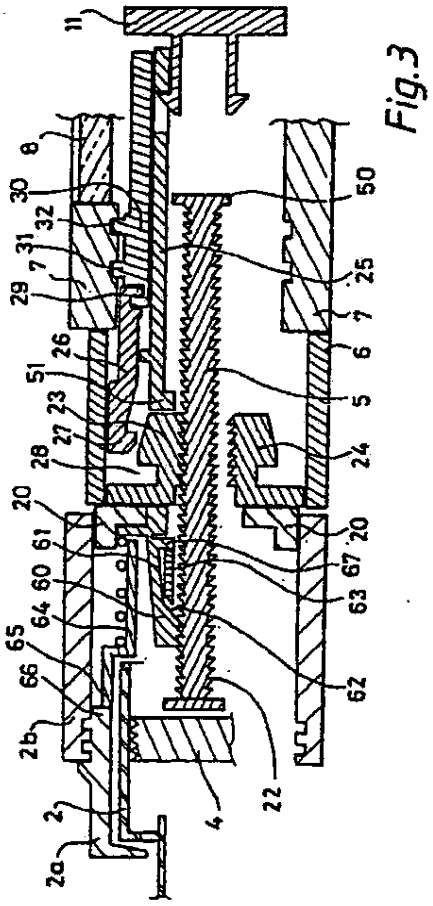
Fig. 2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61
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2b
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2a
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67
63
62

Fig.3

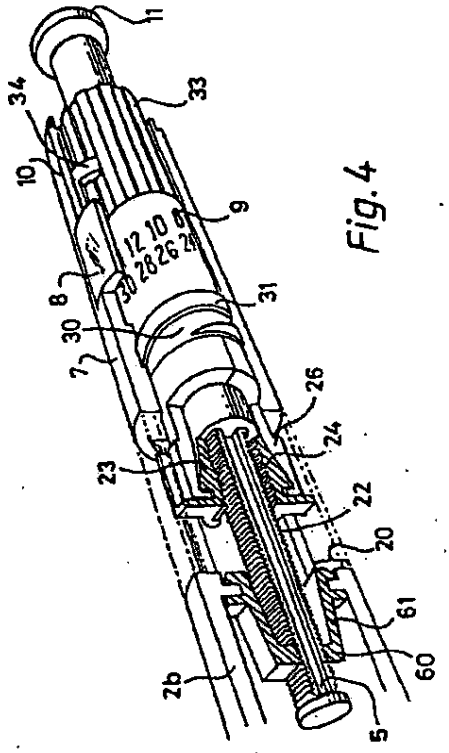

Fig. 4

MEASURED DOSE DISPENSING DEVICE

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of copending U.S. patent application Ser. No. 07/081,241, filed Aug. 4, 1987 now abandoned. The entire text of this application Ser. No. 07/081,241 is hereby incorporated by reference.

The present invention relates to a measured dose dispensing device.

BACKGROUND TO THE INVENTION

Patients suffering from diabetes often have to inject themselves with frequent doses of insulin and this can be done using a conventional syringe. However, the patients often also suffer from side effects of their illness and are not capable of accurately controlling the operation of such a syringe. It is therefore desirable that they should be provided with means for automatically administering an accurately controlled dosage. However, the dosage required by different patients can vary over quite wide ranges, from for example 2 units of insulin per dose to 30 or more units, and it is necessary to ensure that any device is capable of selecting a range of dosages simply and accurately.

Many forms of dispensing device use a pawl and ratchet mechanism to connect a push button or trigger operated by the user to a plunger driving a piston in the barrel of the syringe or a cartridge carried by the device. This achieves a positive drive on the forward stroke, but allows the button or trigger to be retracted, for example under the bias of a return spring, with the pawl riding over the teeth of the ratchet, in readiness for the next actuation of the device. The drive between the pawl and the ratchet is thus never fully disengaged. Typical of such devices are those described for example in U.S. Pat. Nos. 1997129, 2605763, 2718299, 3517668, 3894663, 3977574, 4022207, 4099549, 4415101, 4457712 and 4470317; French Patent Specifications Nos. 1445659, 1170312 and 1149735; and German Patent Specification No. 730971.

Where any provision is made for selecting the volume of fluid to be dispensed, this is usually by way of stops limiting the depression of the push button or trigger operating the device.

European Patent No. 0037696 describes a device in which positive drive between the plunger and the push button is achieved by having ratchet teeth along the length of the plunger into which engage the co-operating teeth of a spring loaded pawl member carried on an axially operated push member extending through the rear end of the device. A stop engaging in a slot in the push member limits the extent of travel of the push member and the volume of fluid to be dispensed is selected by withdrawing the push member the required distance from the forward extreme of its travel with the pawl riding over the teeth of the ratchet. The dose is administered by depressing the push member which carries the plunger with it. Once the plunger has reached the forward extreme of its travel and the container has been emptied, the pawl automatically disengages from the plunger to allow the plunger to be fully retracted to permit a new container to be fitted to the device.

In the above forms of device, an essential feature of the design is that the pawl is free to ride over the teeth

of a ratchet as the pawl is retracted and the drive is thus not fully disconnected from the ratchet so as to be ready for driving the ratchet forward in the next delivery stroke of the device. Firstly, this does not permit a user to correct any error in setting the extent of retraction where this is used to set the amount of fluid to be dispensed. As a result, if too large a retraction has been permitted, the whole of the incorrect dose must be discharged before the device can be correctly set. Secondly, by automatically retracting the pawl in readiness for the next dose, the device is put into a "cocked" condition, which means that a user can operate the device accidentally. Thirdly, we have found that where the user is weak he may not depress the push button or trigger completely or smoothly. This may allow the pawl to retract partially or completely before it has reached the full extent of its forward travel. It will therefore appear to the user that the full dose has not been administered and he will then continue to depress the push button or trigger for its full travel. As a result, the user may administer an overdose, which could be fatal.

GB Specification No. 21096904 A describes a dispensing mechanism in which the plunger has an external screw thread and fits within an internally screw threaded fixed sleeve. The plunger is rotated by a drive cap so as to move the plunger axially. The cap incorporates a pawl and ratchet mechanism so that the cap can be rotated in one direction without rotating the plunger, but rotates the plunger in the opposite direction. The volume of fluid to be dispensed is set by rotating the cap in the first direction the desired amount from a zero point. The dose is dispensed by rotating the cap in the opposite direction back to the zero. Whilst this device is not automatically returned to the "cocked" position after each use, it is cumbersome to use, especially when the user is injecting fluid single handedly into his posterior. Furthermore, since the drive between the cap and the plunger is not fully disengaged, the device can be pumped by repeated rotation and contra-rotation of the cap. It has been proposed in PCT Published Application No. WO 85/02546 to operate a syringe using an electric stepper motor to advance the plunger in the syringe a predetermined amount. This may reduce the risk that an incorrect or excessive dose is dispensed, but such a device is expensive and cumbersome and is not suited for carriage upon the person or for general use.

It has further been proposed, for example in Swiss Patent No. 293302 and U.S. Pat. No. 2695023, to use an automatically engaging latch to limit the travel of the plunger of a syringe to the distance between adjacent notches on the plunger into which the latch engages. This permits the user to dispense only single doses. Where multiple doses are required, the user must repeatedly actuate the latch and must count and remember the number of times he has actuated the latch. This is awkward and often a user cannot remember correctly the number of times he has operated the latch, leading to inaccurate doses.

A further problem with the above devices is that a user cannot determine accurately how much insulin or other medicament is left in the body of the syringe or cartridge and hence whether he can achieve the next dosage completely from that syringe or cartridge or whether he must use a fresh one to achieve the complete dose. Mere visual inspection through the transparent wall of the container is usually too inaccurate to be able

to distinguish between, say, 8 and 14 units of insulin remaining in the container and some more accurate guide is required.

As a result, a need still exists for a simple measured dose dispensing device which can deliver accurately controlled but variable doses of fluid and which can be used single handedly by weak or infirm users without the risk of "pumping" the device to administer an overdose.

SUMMARY OF THE INVENTION

Accordingly, the present invention provides a hand portable device for dispensing a fluid from a container by means of the axial movement of a piston within the container under the influence of a plunger moved by the device, which device is adapted to receive the container at its forward end and to move the plunger axially forward toward or within the container so as to dispense a selected amount of fluid from the container upon each actuation of the device, characterised in that the device comprises:

i. a disengageable drive mechanism adapted to be reciprocated substantially co-axially of the device and adapted to positively engage the plunger whereby the plunger can be moved axially forward by the drive mechanism and adapted to be disengaged from the plunger to permit relative axial movement between the drive mechanism and the plunger;

ii. a disengagement means for selectively engaging and/or disengaging the drive mechanism from the plunger;

iii. an actuation means, which may be integral with or separate from the disengaging means, for actuating the disengagement means, which actuation means requires a positive operation from a user of the device to engage and/or disengage the drive mechanism from the plunger; and

iv. means for selecting the extent of travel of the drive mechanism so as to control the extent of axial movement of the plunger upon actuation of the device.

The device of the invention reduces many of the problems associated with designs proposed hitherto by using a drive mechanism which can be disengaged from the plunger at any point during its travel, notably for the dose selection step. This allows errors in the dose selection to be corrected before the drive is re-engaged. The drive mechanism is locked onto the plunger for the forward stroke of the mechanism, so that the plunger or drive mechanism cannot be partially retracted during the forward stroke, which reduces the risk of administering an overdose. The engagement and/or disengagement of the drive mechanism requires a positive operation to be carried out by the user, so that the device can be left in the de-activated state until the next dose is required and cannot be operated until the positive drive engagement operation has been carried out. However, once the dosage has been selected and the drive has been re-engaged, the device can readily be used single handedly, notably when a dose is being injected into the user's posterior.

The container upon which the device of the invention is to be used can be a conventional syringe body, but is preferably a generally cylindrical cartridge containing the fluid to be dispensed. As indicated above, the invention is of especial use in the self-administration of a medicament, notably insulin, by a user. For convenience, the invention will be described hereinafter in terms of this use.

The medicament is preferably contained in a cartridge, notably one with a comparatively short wide body, typically from 0.3 to 3 cms external diameter and from 3 to 7.5 cms long. The cartridge has one end closed by a transverse membrane or wall, the other being closed by the axially moveable piston. If desired, the one end can carry a hypodermic needle or the like already in position, or this can be provided as a separate component which is secured in place when the cartridge is mounted on the device of the invention. For convenience, the invention will be described hereinafter in terms of the use of a cartridge of insulin.

The cartridge may be mounted at the forward end of the device by any suitable means, for example as a push, screw, bayonet or other fit within an axial socket at the forward end of the device. The socket can contain other components of the device which are to co-operate with the cartridge, for example a mechanism for preventing the plunger from moving rearwardly as described later. It is particularly preferred to provide an internal circumferential annular shoulder or series of projections which act as a stop against which the rim of the cartridge seats when fully home in the socket, thus correctly positioning the cartridge axially in the device.

The cartridge is preferably mounted within a detachable housing which is a screw or other fit into the device, for example into the axial socket. The use of such a housing aids correct mounting of replacement cartridges in the device. By making the housing from a clear plastic material, a user can readily observe the movement of the piston within the cartridge and can assess the amount of fluid in the cartridge. The housing also provides a measure of protection to the cartridge, both physical and against pathogenic organisms and other possible contamination.

Where such a housing is used, the needle end of the cartridge can project through a terminal aperture in the housing or that end of the housing can be closed and can carry a needle or other outlet integrally therewith which projects axially inwardly into the housing to penetrate the membrane at the end of the cartridge.

The cartridge houses the piston which is to be moved by the plunger. This piston can be of conventional design and will usually form part of the cartridge as commercially available. The plunger acts on the piston and the piston can carry a socket or other recess to receive and locate the head of the plunger. In some cases, the plunger can be affixed to the piston and will form part of the cartridge as supplied, in which case the plunger will extend into the device when the cartridge is mounted on the device. However, it is preferred that the plunger form part of the device rather than of the cartridge and, for convenience, the invention will hereinafter be described with respect to this configuration.

The device typically comprises a substantially cylindrical hollow housing containing the various mechanisms of the device as described below assembled substantially co-axially around the plunger.

The plunger is preferably a simple elongated rod which extends axially along the longitudinal axis of the device and can have a substantially circular, polygonal, squared or other cross-section as desired. Thus, the plunger may have two or more opposed flatted faces and/or can have two, or more axial grooves in its surface to assist angular location of the plunger with respect to the other components.

The plunger can have a plain surface onto which the drive mechanism acts by a frictional grasp, as when a

Torrington type mechanism is used. However, it is preferred that the plunger carry an axial series of transverse ribs, grooves or teeth which engage with corresponding teeth carried by the drive mechanism. The teeth can extend for substantially the full length of the plunger, but this need not be the case and the terminal portions of the plunger can have a plain surface. Preferably, the teeth are of a saw tooth form with the scarp or undercut face of the tooth facing rearwardly. It is preferred that the axial distance between adjacent teeth corresponds to the distance the piston is to move in the cartridge to dispense a unit dose, for example 1 or 2 IUs, of insulin.

The drive mechanism for present use is one which can be completely disengaged from the plunger to permit relative axial movement between them and so that there can be no drive between the drive mechanism and the plunger until the drive is positively re-engaged. However, when the drive mechanism is engaged, it locks onto the plunger so that there is substantially no relative movement between them. A suitable drive mechanism may thus incorporate a mechanism which engages and disengages by radial movement, for example a Torrington type drive in which a series of ball or roller bearings are carried in a tapered cup around the plunger. A plug member can be moved axially into the taper to drive the balls further into the taper and thus radially inwardly to clamp onto the plunger.

However, a particularly preferred drive mechanism comprises two or more jaws arranged substantially symmetrically around the plunger and which can be moved radially inwardly to clamp onto the plunger. The radially inward faces of the jaws preferably carry teeth which co-operate with those carried by the plunger to provide a positive locked drive between the drive mechanism and the plunger when the drive is engaged. The teeth on the jaws preferably have a similar shape to those on the plunger so that there is a positive fit between them.

The jaws or other mechanism for making the positive drive connection between the drive mechanism and the plunger are preferably carried on a split collet type of structure so that they are journalled upon the plunger and can move axially thereon when disengaged. The jaws are normally urged apart by a compression spring or other bias means acting radially outwardly so that they adopt the disengaged position. In a preferred construction, the jaws extend transversely to either side of the plunger and a transverse coil compression spring is held between the jaw extensions at each side of the plunger. The springs can be held within a retaining extensible saddle piece formed integrally with each jaw extension for ease of assembly of the jaw mechanism. Alternatively, the jaws can be carried via leaf spring mountings from the collet or from another part of the drive mechanism.

Means are provided whereby a user can move the drive mechanism axially to set the dose required and to drive the plunger forward. Preferably, the forward drive is by means of a button or the like operatively associated with the plunger and extending axially from the rear end of the device, but others forms of forward drive means can be used. For example, the drive mechanism or a part operatively associated therewith can carry a radial arm which extends through an axial slot in the housing of the device, or a screw type mechanism can be used.

However, a particularly preferred form of drive mechanism comprises the radially moveable jaws described above carried by a split collet assembly journalled on the plunger and having springs or other bias means for urging the jaws radially outwards. The collet or the rear faces of the jaws themselves are acted on by an axially reciprocateable push sleeve journalled upon the plunger. The push sleeve extends rearwardly to provide a push button mounting projecting from the rear of the device so that depression of the button causes the push sleeve and hence the jaws to move axially to drive the plunger forward. If desired, the push button or push sleeve can be recessed within the terminal portion of the housing so that a user must insert some implement, for example a removable nose cap protecting the needle of the cartridge, to be able to operate the forward drive.

The drive mechanism is engaged or disengaged by some means which requires a positive operation by the user of the device so that the drive cannot be accidentally actuated or over-ridden. Thus, where the plunger has two or more flatted surfaces, these can be inset radially from the non-flatted surfaces so that the teeth on the jaws, or the balls in a Torrington type drive coupling as described above, would not engage the flatted surfaces. The drive can therefore be disengaged by rotating the jaws or a part operatively associated therewith, for example the push sleeve described above, to align the jaws with the flatted faces, or vice versa, by a tangential movement. In this position the drive mechanism is disengaged and can move relative to the plunger, for example when it is desired to set the dosage to be dispensed. The positive operation required by the user is to rotate the push sleeve or the protruding push button connected thereto with respect to the drive mechanism and this action has to be reversed before the drive can be re-engaged.

However, a preferred form of disengagement mechanism is a cam or other radially acting mechanism which moves the drive mechanism radially in and out of engagement with the plunger. Thus, the opposed jaws described above can be moved in and out by a cam carried internally on a rotating sleeve portion of the housing within which the operating mechanism of the device is housed. In this case, the rotatable sleeve section provides both the disengagement means (the internal cams) and the actuation means (the section of the housing itself carrying the cams) in a single member.

The cams acts against the spring or other bias holding the jaws clear of the plunger and brings the jaws into engagement with the plunger. The cams also retain the jaws in the engaged position, thus locking the drive connection between the drive mechanism and the plunger, until the cams are released by rotating the sleeve section carrying them. Alternatively, the jaws can be tied to the cams so that they are moved radially in both directions by the cams without the need for a spring bias. A further form of drive disengagement and actuation mechanism is an axial or tangentially mounted lever which is mounted by means of a pivot within the wall of the housing. Raising one end of the lever causes the other end to bear radially against the jaws or other radially moveable component of the drive mechanism either directly or via an intermediate component so as to urge them radially inward and into engagement with the plunger.

Where a rotatable cammed housing section is used, it is preferred that the exterior of this section carry mark-

ings or have an oval cross-section so that a user can tell the orientation of the section simply by touch.

The device incorporates a dosage selection mechanism for selecting the extent of axial travel of the disengaged drive mechanism so as to control the movement of the plunger and hence the volume of fluid discharged from the cartridge. The drive is then re-engaged and the drive mechanism returned to the datum point carrying the plunger with it. In this way the plunger moves an amount which is set by the extent to which the drive mechanism is retracted from a datum point. Since the drive is disengaged during the retraction of the drive mechanism, it is possible to correct any over- or undershoot in the movement of the drive mechanism before the drive is re-engaged. Also, once the drive has been re-engaged, due to the fact that the plunger does not readily move rearwardly, as described below, the user cannot retract the drive mechanism or the plunger without positively disengaging the drive again. Hence tremulous or jerky operation of the device will not affect the dose to be dispensed.

The datum point for the dosage setting mechanism is preferably a stop determining the extent of forward travel of the drive mechanism or a part operationally associated therewith. Thus, the abutment of the push button driving the push sleeve against the end of the housing can provide that datum point. However, it is preferred that the datum point be provided by a stop located within the device against which the front face of the drive mechanism buts at the forward extreme of its travel. Conveniently, this stop is also the stop against which the rim of the cartridge seats when it is fitted to the device, so that the stop serves as the datum point both for positioning the cartridge to one side and for the dosage selection mechanism on the other.

The dosage selection means can operate axially, as when the push sleeve engaging the jaws described carries one or more external radial projections which but against co-operating projections carried by the housing within which the sleeve reciprocates. Rotation of the housing selects which stops will engage and hence the length of travel of the drive mechanism. Alternatively, the dosage selection mechanism can take the form of a side arm carried by the push sleeve and protruding through a stepped track or aperture in the wall of the housing which allows the sleeve to be retracted for the full length of one axial section of the track. The sleeve or a part operatively associated therewith then has to be rotated to allow the arm to move transversely into the next section where a larger dose is required.

However, we have found that a screw mechanism provides a particularly effective and accurate means for retracting the drive mechanism. Thus, for example, the dosage selection means utilises a screw sleeve journalled upon the push sleeve. The screw sleeve carries an external projection or screw thread which co-operates with an internal screw thread on the housing wall. Alternatively, the screw sleeve can have a radial projection which is journalled in a helical track or aperture in the wall of the housing of the device, or vice versa.

The screw thread can have any suitable pitch having regard to the axial movement required to achieve the minimum dose to be administered. The optimum pitch can readily be determined by simple trial and error having regard to the geometry of the device, for example so that ¼th of a turn of the screw sleeve achieves an axial travel corresponding to the axial distance between adjacent teeth on the plunger.

The screw sleeve has means by which it can be rotated by the user, for example by means of a pin or arm projecting through the wall of the device; or preferably by a collar located adjacent the end of the housing. This is connected to the sleeve through a spline coupling or the like to allow relative axial movement between the collar and the sleeve.

The forward movement of the plunger may be achieved by returning the dosage selection mechanism, for example the screw sleeve, to the datum point when the drive is re-engaged. However, this may not be easy or convenient, notably where this requires the user to rotate part of the device to achieve this, and it is preferred to employ an axial push action, e.g. by means of the push sleeve as described above. We therefore prefer that the dosage selection mechanism be demountably connected to the drive mechanism so that, when the drive is re-engaged, the connection between the dosage selection and the drive mechanisms is released. This can be conveniently achieved by providing a latch mechanism at or adjacent the forward end of the dosage selection mechanism, e.g. the screw sleeve, which latch mechanism engages the drive mechanism when the latter is in the disengaged position but which releases the drive mechanism when the latter is in the engaged position. The drive mechanism can then be driven forward independently of the dosage selection mechanism. Suitable latch mechanisms can readily be devised having regard to the specific design of the device they are to fit.

The device also comprises means whereby the dosage corresponding to a selected extent of retraction of the drive mechanism can be observed aurally or visually by a user, for example by means of a clicker mechanism. Preferably, the push sleeve or the screw sleeve carries markings correlating the dosage with the extent of axial movement. Where a screw sleeve is used, the markings are carried along a spiral path and are progressively brought into register with a window or port in the wall of the housing so that the user can see what dose is to be dispensed.

In order that a user can determine whether or not sufficient fluid remains within the container to achieve a stated amount to be dispensed, it is preferred to provide a second stop means carried by the plunger, for example at the rearward end thereof, which is engaged by the drive mechanism or push member as it is retracted. The second stop will prevent the drive mechanism or push member from being withdrawn to its full extent if the residual potential travel of the plunger is less than the desired dose. A user will detect resistance to operation of the dosage selection mechanism or will notice when the spline drive between collar 10 and the screw sleeve is over-ridden when this occurs. The user can then tell from the dose indicated as described above whether there is sufficient medicament in the cartridge to complete the required dose.

As indicated above, the plunger should not be free to move rearwardly during normal use of the device. This can be achieved by ensuring that the plunger is a frictional fit within the device. However, this may require excessive forces to operate the device if the frictional forces are to overcome attempts to retract the plunger when the drive mechanism is engaged. We therefore prefer to provide some form of one way device to provide positive means for preventing the plunger from

moving rearwardly when a cartridge is mounted on the device. Conveniently, this means takes the form of a second pawl arrangement which engages with the teeth on the plunger shank at the forward end of the device. Whilst this pawl can be permanently engaged, it is preferred that it be is biassed so as to be disengaged from the plunger when no cartridge is in position. This enables the plunger to be retracted when a cartridge has been removed from the device so that a new one can be fitted. When the cartridge is mounted on the device, it or its housing causes the second pawl to re-engage with the teeth on the plunger.

The device of the invention can be provided with other features to enhance its use. For example, the device can be put up in the form of a pen type object with a cap over the needle end of the device and a clip for mounting it in the pocket of the user.

From the above, it will be seen that from one aspect, the present invention provides a device for dispensing a controlled amount of fluid from a container, which device comprises an assembly adapted to be mounted upon a container in which a plunger is adapted to be moved axially along the container in increments so as to drive a piston within the container and thus to dispense fluid from the container, characterised in that the assembly comprises a drive mechanism adapted to be reciprocated axially of the device and to be positively engaged with the plunger for the forward stroke of the drive mechanism so as to prevent relative movement between the plunger and the drive mechanism and to move the plunger forward in the container, which drive mechanism requires a positive action to disengage it from the plunger so as to permit relative movement of the plunger and drive mechanism for at least rearward movement of the drive mechanism; in that the forward travel of the drive mechanism is limited by a fixed stop mechanism; and in that the extent of the forward stroke of the drive mechanism is selected by withdrawing the drive mechanism a selected distance from the said fixed stop.

From a preferred aspect, the invention provides a device for dispensing a controlled amount of fluid from a container by means of a piston journalled in said container, which device is characterised in that it comprises:

a. an elongated generally cylindrical hollow body member having its forward end adapted to receive and retain the fluid container;

b. a plunger extending axially within said body member and adapted to be moved axially in a series of individually selected increments and to bear against the piston within the container when mounted on the said body member so as to move the said piston to dispense doses of fluid from the container at each incremental movement of the plunger;

c. a radially acting jaw member adapted to be moved into engagement with the said plunger to provide a positive drive connection between said jaw and said plunger, and to be disengaged from said plunger so as to permit relative axial movement between said plunger and said jaw;

d. means requiring positive operation by a user of the device for engaging or disengaging said jaw from said plunger.

e. an axially acting push sleeve journalled upon said plunger for moving said jaw forward when engaged to said plunger;

f. axially acting dosage selection means comprising a screw thread moved sleeve journalled for axial movement upon said push sleeve and carrying demountable means for engaging said jaw when said latter is disengaged from said plunger and for moving it rearwardly from a datum point so as to select the possible extent of forward travel of said plunger and to release said jaw when said jaw is re-engaged with said plunger for axial movement by said push sleeve; and

g. means for rotating said screw sleeve so as to select the extent of rearward movement of said screw sleeve from said datum point.

The invention also provides a device of the invention having mounted thereon a container, notably a cartridge, containing a medicament; and a medicament cartridge for use with the device, notably one housed within a housing adapted to be secured to the front end of the device of the invention.

The invention yet further provides a method for administering a fluid medicament to a patient using a device of the invention.

DESCRIPTION OF THE DRAWINGS

The device of the invention will now be described by way of illustration with respect to a preferred form thereof as shown in the accompanying drawings in which

FIG. 1 is an overall external diagrammatic view of the device;

FIG. 2 is a cross-sectional diagrammatic view through the device of FIG. 1;

FIG. 3 is a cross-sectional diagrammatic view through an alternative form of the device showing some of the components in greater detail; and

FIG. 4 is a part cut away/part perspective view of the device.

DESCRIPTION OF A PREFERRED EMBODIMENT OF THE INVENTION

The device comprise an elongated generally cylindrical housing 1 having an axial socket at one end into which a generally cylindrical cartridge 2 can be screw or push fitted. The cartridge typically has a cylindrical clear plastics or glass barrel with a hypodermic needle 3 protruding substantially co-axially from the free end thereof. A piston 4 journalled within the cartridge 2 is incrementally moved by a plunger 5 extending substantially co-axially rearwardly into the housing 1 of the device. The plunger 5 is separate from the piston and forms part of the device of the invention.

As shown in FIG. 3, the cartridge 2 can be housed in a housing 2a which is a screw fit into a collar 2b extending axially from the front end of the housing 1.

The rim of the cartridge seats against a circumferential radial shoulder or series of radial projections 20 carried internally by the housing 1 so as to locate the cartridge at a consistently fixed position with respect to the dosage selection mechanism as described below.

The device is provided with a pawl type one way mechanism which engages teeth on the plunger so as to prevent rearward movement of the plunger 5 once the cartridge is in place. This one way mechanism is shown diagrammatically as 21 in FIG. 2 and is biassed to retract radially when the cartridge is removed. For example, the housing can incorporate a twist mechanism which both locks the cartridge in position and actuates the one way mechanism; or the rim of the end of the cartridge or its housing can bear against part of the one way mechanism as it seats home to actuate the one way mechanism. The one way mechanism disengages when

the cartridge is removed to allow the plunger 5 to be retracted into the device to permit a new cartridge to be mounted on the device.

A preferred form of the one way mechanism 21 is shown in FIG. 3 and comprises a pair of diametrically opposed pawls 60 carried on spring arms 61 snap fitted onto the annular shoulder 20 to extend forward of the shoulder into the axial socket in which the cartridge is mounted. The pawls 60 have an inclined rearward face 62 which bears against a correspondingly angled face carried by a split collet 63 mounted around the plunger shank and radially inward of arms 61. The collet is attached to a spring loaded sleeve 64 which is a slideable fit within the socket and is spring biassed into its forward position. The front end of the sleeve 64 provides a stop 65 against which the rim 66 of the housing 2a bears as it is mounted in the device. This causes the sleeve 64 to be moved axially rearwardly to carry the inclined face of collet 63 clear of the inclined face 62 of the pawl and to bring the rear edge of collet 63 into contact with a stop 67 carried on the radially inward face of arm 61. This causes the arm 61 to flex radially inward and urge pawl 60 into engagement with the teeth on the plunger. When the housing 2a is removed to fit a new cartridge 2, this allows the sleeve 64 to move forward under the thrust of the spring so that collet 63 moves forward to release stop 67 and bears against the inclined face 62 to lift the pawl 60 clear of the teeth on the plunger. The plunger can now be retracted into the device to enable another cartridge to be fitted. By using the rear of the accurately moulded housing 2a to actuate the pawl mechanism 60–67, rather than the rim of the cartridge 2, variations in the size of the cartridge can be accommodated.

Rearwardly of shoulder 20, the body of the device houses the plunger drive mechanism, the means for engaging and disengaging the drive mechanism from the plunger and the dosage selection means. In the form of the device shown, these take the form of a series of members concentrically journalled around the plunger 5.

As shown, the housing comprises a rotatable section 6 which houses the drive engagement mechanism; a fixed section 7 containing the dosage selection mechanism and having a port 8 through which a scale 9 indicating the dose selected can be seen by the user; a further rotatable collar or sleeve 10 for operating the dosage selection mechanism; and a terminal axially operating push button 11 for driving the plunger forward to dispense the selected dose. The various sections of the housing can have any desired external shape, but it is preferred that the housing 1, sleeve 6 and section 7 have an oval external cross-section so that the relative rotational position of one with respect to the other can readily be detected by a user, notably by a blind person.

The plunger 5 preferably has a substantially circular cross-section, but can have a squared, triangular or other cross-section shape if desired. For example, as shown in FIG. 4, it may have two opposed flats along its length to guide the drive means.

The plunger 5 carries a series of circumferential ribs or teeth 22 which form an axial ratchet into which the one way mechanism 21 and the radially clampable drive mechanism described below engage. The teeth 22 are of a saw tooth form with the scarp face of the teeth directed rearwardly. Preferably, the teeth extend axially for the full length of the plunger 5. As indicated above, it is preferred that the axial distance from one tooth to the next corresponds to a dosage unit for the material being dispensed.

Located to the rear of shoulder 20 is the drive mechanism and the mechanism for engaging and disengaging this from the plunger. The drive mechanism is a pawl type mechanism which is radially engageable and disengageable with the teeth on the plunger and comprises two jaws 23 and 24 diametrically opposed to one another and carrying on their radially inward faces teeth which correspond to and engage with the teeth 22 on the plunger.

The jaws are normally urged radially outwardly, as shown for jaw 24 in FIGS. 2 and 3, by transverse coil springs acting between the jaws 23 and 24 or by other bias means (not shown) so that their teeth do not engage those of the plunger, which is then free to move axially with respect to the jaws when they are in their outward position, but is locked to the jaws when they are in their radially inward position, as shown for jaw 23 in FIGS. 2 and 3.

The jaws are moved radially inward against the thrust of the coil springs by a pair of cams 6a carried on the internal face of the rotatable section 6 of the housing or formed by the narrower diameter sectors of the oval cross-section of the rotatable section 6. The user has to twist section 6 to engage or disengage the jaws from plunger 5 and thus engage or disengage the drive to the plunger. If desired, section 6 can be spring biassed towards the drive disengaging position so that the user always has to twist section 6 before the device can be used.

The shoulder 20, as shown in FIGS. 1 and 3, defines the forward limit of the travel of the drive mechanism and provides the datum point from which the dosage is determined. In the device shown in FIGS. 2, 3 and 4, the forward faces of jaws 23 and 24 but against the rear face of shoulder 20 to set the zero or datum point for the dosage selection mechanism.

A push sleeve 25, journalled on plunger 5 and within the dosage selection mechanism described below, acts axially on the rear faces of the jaws 23 and 24 when in their drive engaged position to drive the jaws and hence the plunger 5 forward. When the jaws are in the drive disengaged position, they still bear against the push sleeve so that they carry it axially rearwards with them during the dosage selection. The push sleeve 25 provides the mechanical link between the terminal push button 11 which a user presses and the jaws 23 and 24.

The jaws 23 and 24 are moved axially by means of a split jaw drive sleeve 26 which has forward hooks 27 which engage similar recesses 28 at the rear of the jaws and rearward hooks 29 or other flexible linkages which connect the sleeve 26 axially to the forward end of the screw sleeve 30 of the dosage selection mechanism. When the jaws are in the drive disengaged position as shown for jaw 24 in FIGS. 2 and 3, the hooks 27 and recesses 28 are engaged and the jaws can be moved axially with the screw sleeve 30. When the jaws are in the drive engaged position, as shown for jaw 23 in FIGS. 2 and 3, the hooks 27 are released from recesses 28 to permit the jaws to move axially with sleeve 25 and free from the screw sleeve 30 (as shown in FIG. 3).

The dosage selection mechanism is housed within section 7 of the housing and comprises a screw sleeve 30 journalled for rotation and axial movement upon push sleeve 25. Sleeve 30 carries an external screw thread 31 which engages a similar thread 32 carried internally by section 7 of the body of the device. Sleeve 30 is rotated

and thus caused to move axially by means of collar 10 driving the sleeve through a spined drive 33 shown in FIGS. 2 and 3. Collar 10 or the window insert in port 8 preferably has a ratchet or clicker mechanism 34 to give an audible indication as the dose is selected.

Retraction of sleeve 30 carries the jaw drive sleeve 26 and the jaws 23 and 24 with it when they are in the disengaged position and the dose selected can be seen through port 8. Re-engagement of jaws 23 and 24 with the plunger, breaks the latch 27/28 and allows the push sleeve 25 and the jaws 23 and 24 to move independently of the screw sleeve 30 and the jaw drive sleeve 26.

To indicate when there is insufficient fluid left in the cartridge to achieve the next dose, a radial shoulder or stop 50 is located at or adjacent the rearward end of plunger 5. This co-operates with a corresponding stop or shoulder 51 at the forward end of the push sleeve 25. The stops engage when the push sleeve is retracted to the maximum extent possible as the plunger 5 approaches the extreme of its forward travel. The user can then see from the dose displayed at the port 8 whether the cartridge contains the requisite amount of fluid. Since the plunger drive is not engaged at this time, the user can then set the dosage mechanism to the required dose if this is less than the amount indicated as remaining in the cartridge without having to discharge fluid as with a conventional device.

Push sleeve 25 is provided with a push button end cap 11 protruding axially from the body of the device which the user depresses to drive the sleeve 25 forward within the housing until the front faces of jaws 23 and 24 but against the rear of shoulder 20. The jaws 23 and 24 can only be moved rearwardly when they have been disengaged from the teeth 22 on the plunger 5, since the one way mechanism 21 will prevent rearward movement of the plunger 5. If a user attempts to set the dosage mechanism whilst the drive is engaged, he will detect resistance to rotation of sleeve 10. If he ignores this, the spline drive 33 between collar 10 and the screw sleeve 30 will be over-ridden to release the screw sleeves to prevent damage to the mechanism. However, unless the drive is engaged, depression of button 11 will not achieve any forward movement of the jaws or discharge of fluid from the cartridge 2.

The above device can be manufactured in many suitable materials and readily lends itself to manufacture by injection moulding of suitable plastics materials with the various components being snap fits upon one another.

In operation, a user rotates the sleeve 6 to disengage the drive mechanism. Jaws 23 and 24 should be seated against the rear face of shoulder 20, the zero setting, from the previous use of the device, but the screw sleeve 30 will be at the dosage position previously selected. The user can thus see what dose was last administered where a sequence of different doses has to be administered. Sleeve 10 is rotated, say clockwise, to bring sleeve 30 to its forward position at which the latching mechanism 27/28 engages the jaws 23 and 24 and seats them firmly against the rear face of stop 20. The engagement of the latches can be used to provide an audible signal when this occurs, or the resistance to further forward movement will provide the signal to the user that the zero setting has been reached. The dosage displayed through port 8 will now read zero.

Sleeve 10 is then rotated anti-clockwise the desired number of turns, as evidenced by the number of clicks heard or by the dose displayed at the port 8, to retract screw sleeve 30, the jaw drive sleeve 26 and the jaws 23 and 24 and the push sleeve 25 the desired distance with respect to plunger 5. This will also cause the push button 11 to be extended from the rear end of the device.

Sleeve 6 is then rotated to re-engage the positive drive between the push sleeve 25, the jaws 23 and 24 and the plunger 5. This action will also disengage the latch 27/28 between jaws 23 and 24 and the jaw drive sleeve 26. At this point the device is cocked and ready to dispense the desired dose from the cartridge. However, the device has required a series of positive actions to achieve this state and would not normally be retained by a user in the cocked state, but would be stored with the drive disengaged so that accidental actuation of the device can not occur.

The user then inserts the point of needle 3 into his arm, buttock or other suitable point in his body and depresses button 11 to administer the dose of insulin. The dose is administered by depressing the button fully. If the button is not depressed fully, the user can detect this and can complete the dose administration. If desired, a coloured band can be mounted around button 11 which will remain partially exposed until the button is fully depressed. Release of pressure on button 11 does not allow the plunger 5 to retract as with previous designs, so that jerky or interrupted depression of button 11 does not allow the user to pump the device to administer an excessive dose.

When the full dose has been administered, the jaws 23 and 24 will but against the rear of shoulder 20. Due to the action of the one way mechanism 21, 60–67, the blocks 23 and 24 can not be retracted and administration of a further dose of insulin is not possible until the whole process of dose selection and re-cocking of the device is carried out. The device will therefore resist accidental overdosing due to repeated pressing of button 11.

As stated above, the device of the invention finds use wherever it is desired to provide a measured dose syringe, for example in the administration of Other medicaments or in dispensing accurately known amounts of a fluid, for example in blood tests or analytical work. It will also be appreciated that the device may be altered in ways which do not affect the fundamental operating concept of the device, for example by using a short plunger within the device to drive an intermediate plunger linked to a plunger carried by the piston of the cartridge; or to incorporate a flexible drive between the plunger 5 and the piston 4 so that the device of the invention is mounted at an angle to the axis of the cartridge.

What I claim is:

1. A device for dispensing a controlled amount of fluid from a container, which device comprises an assembly adapted to be mounted upon a container in which a plunger is adapted to be moved axially along the container in increments so as to drive a piston within the container and thus to dispense fluid from the container characterised in that the assembly comprises a drive mechanism adapted to be reciprocated axially of the device and to be positively engaged with the plunger for the forward stroke of the drive mechanism so as to prevent relative movement between the plunger and the drive mechanism and to move the plunger forward in the container, which drive mechanism requires a positive action to disengage it from the plunger so as to permit relative movement of the plunger and drive mechanism for at least rearward movement of the drive mechanism; in that the forward travel of the drive

mechanism is limited by a fixed stop mechanism; and in that the extent of the forward stroke of the drive mechanism is selected by withdrawing the drive mechanism a selected distance from the said fixed stop.

2. A device as claimed in claim 1 which comprises:

a. a hollow body member having one end adapted to receive and retain the fluid container

b. a plunger carried by said body member and adapted to be moved axially in a series of increments and to bear against the piston within the container so as to move the said piston to dispense doses of fluid from the container at each incremental movement of the plunger

c. a push member carried by said body member for axial movement with respect to said body member and having means for achieving positive engagement with the said plunger in the forward direction of travel of the push member

d. means requiring positive operation for releasing said positive engagement and thus permitting relative axial movement between the push member and the plunger in at least the rearward direction of travel of the said push member

e. a stop means against which the push member or a part associated therewith butts at the extreme of the plunger's forward travel on each of its incremental movements

f. means for withdrawing the push member or its said associated part axially from the stop means to a selected distance whereby the extent of each incremental forward movement of the plunger can be selected

g. means for inhibiting rearward movement of the plunger whilst the container is located upon the body member

3. A device as claimed in claim 2 wherein there is provided a second stop means carried by said plunger which is engaged by the drive mechanism as it is retracted whereby the second stop member prevents the drive mechanism from being withdrawn to its full extent if the residual potential travel of the plunger is less than the desired dose.

4. A device as claimed in claim 1 wherein means are provided whereby the inhibition of the rearward movement of the plunger is removed or released when the container is removed from the body member.

5. A device as claimed in claim 4 wherein rearward movement of the plunger is prevented by a ratchet mechanism which is engaged by rotating part of the body member which also locks the container in position.

6. A device as claimed in claim 1 wherein the positive drive between the plunger and the drive mechanism is achieved by means of a radially acting mechanism which engages the shank of the axially reciprocable plunger member.

7. A device as claimed in claim 6 wherein the plunger has a series of ratchet teeth along its outer surface which are engaged directly or indirectly by a radially expansible toothed clamp member carried terminally by a sleeve push member journalled for axial movement within the device.

8. A device as claimed in claim 7 wherein the sleeve member is moveable axially by rotation thereof using a screw thread mechanism.

9. A device as claimed in claim 6 wherein the radially acting mechanism is actuated by rotation of a cam or similar mechanism to drive the radially acting mechanism radially inwardly into engagement with the plunger.

10. A device for administering insulin from a cylindrical cartridge having a piston journalled therein for axial movement along the cartridge to dispense the insulin contents of the cartridge through a needle outlet into the body of a user, which device comprises:

a. a cylindrical hollow body member having one end adapted to receive and retain the cartridge

b. a plunger journalled within the said body member and adapted to be moved axially in a series of increments and to bear against the piston within the container so as to move the said piston to dispense discrete and selectable doses of insulin from the cartridge at each incremental movement of the plunger

c. a generally cylindrical push sleeve journalled within the said body member for axial movement with respect to said body member

d. a pair of opposed clamp members mounted for radial movement within the said body member and which can be moved radially inwardly to positively engage the said plunger in the forward direction of travel of the push sleeve whereby the plunger is driven forward by the said sleeve, but which can be moved radially outwardly to disengage from the said plunger for the rearward movement of the said sleeve to permit relative axial movement between the push sleeve and the plunger in at least the rearward direction of travel of the said push sleeve

d. cam means operable from the exterior of the said body member and requiring positive operation for moving the said clamp members radially inward or outward

e. an inwardly directed shoulder within the body member which acts as a stop means against which the push member or the clamp members but at the extreme of the plunger's forward travel on each of its incremental movements

f. an external rotatable member co-axial with the said body member for rotating the said sleeve member and causing it to move axially under the influence of a screw thread mechanism co-operating between the said body and the said sleeve whereby the sleeve can be moved rearwardly to a selected extent from the said stop shoulder when the clamp members are disengaged from the said plunger and thereby select tee extent of forward travel of the plunger when the clamp members are re-engaged with the plunger for forward movement thereof.

11. A hand portable device for dispensing a fluid from a container by means of the axial movement of a piston within the container under the influence of a plunger moved by the device, which device is adapted to receive the container at its forward end and to move the plunger axially forward toward the container so as to dispense a selected amount of fluid from the container upon each actuation of the device, characterised in that the device comprises a drive mechanism adapted to be reciprocated axially of the device and to be positively engaged with the plunger for the forward stroke of the drive mechanism so as to prevent relative movement between the plunger and the drive mechanism and to move the plunger forward, which drive mechanism requires a positive action to disengage it from the plunger so as to permit relative movement between the plunger and drive mechanism for at least rearward

movement of the drive mechanism; in that the forward travel of the drive mechanism is limited by a fixed stop mechanism; and in that the extent of the forward stroke of the drive mechanism is individually selectable for each actuation of the device by withdrawing the drive mechanism or a part operatively associated, therewith a selected distance from a fixed stop defined by said fixed stop mechanism.

12. A hand portable device for dispensing a fluid from a container by means of the axial movement of a piston within the container under the influence of a plunger moved by the device, which device is adapted to receive the container at its forward end and to move the plunger to dispense a selected amount of fluid from the container upon each actuation of the device, characterised in that the device by axially moving said drive mechanism a selected amount relative to said plunger while said drive mechanism is disengaged therefrom comprises:

i. a disengageable drive mechanism adapted to be reciprocated axially of the device and adapted to positively engage the plunger whereby the plunger can be moved axially forward by the drive mechanism and to be disengaged from the plunger to permit relative axial movement between the drive mechanism and the plunger;

ii. a disengagement means for selectively engaging or disengaging the drive means from the plunger;

iii. an actuating means, which may be the integral with or separate from the disengagement means, for actuating the disengagement means, which actuation means requires a positive operation from a user of the device to engage and/or disengage the drive mechanism from the plunger; and

iv. means for individually selecting the extent of travel of the drive mechanism for each actuation of the device so as to control the extent of axial movement, of the plunger upon actuation of the device.

13. A hand portable device for dispensing a fluid from a container by means of the axial movement of a piston within the container under the influence of a plunger moved by the device, which device is adapted to receive the container on its forward end and to move the plunger axially forward towards or within the container so as to dispense a selected amount of fluid from the container upon each actuation of the device, characterised in that the device comprises:

a. an elongated generally cylindrical hollow body member having its forward end adapted to receive and retain the fluid container;

b. a plunger extending axially within said body member and adapted to be moved axially in a series of individually selected increments and to bear against the piston within the container when mounted on the said body member so as to move the said piston to dispense doses of fluid from the container at each incremental movement of the plunger;

c. a radially acting jaw member adapted to be moved into engagement with the said plunger to provide a positive drive connection between said jaw and said plunger, and to be disengaged from said plunger so as to permit relative axial movement between said plunger and said jaw;

d. means requiring positive operation by a user of the device for engaging or disengaging said jaw from said plunger.

e. an axially acting push sleeve journalled upon said plunger for moving said jaw forward when engaged to said plunger;

f. axially acting dosage selection means comprising a screw thread moved sleeve journalled for axial movement upon said push sleeve and carrying demountable means for engaging said jaw when said latter is disengaged from said plunger and for moving it rearwardly from a datum point so as to select the possible extent of forward travel of said plunger and to release said jaw when said jaw is re-engaged with said plunger for axial movement by said push sleeve; and

g. means for rotating said screw sleeve so as to select the extent of rearward movement of said screw sleeve from said datum point.

14. A device as claimed in claim 11 wherein the plunger carries an axial series of transverse teeth and the drive mechanism carries corresponding teeth adapted to engage the teeth on the plunger when in the drive engaged position.

15. A device as claimed in claim 11 wherein the drive mechanism is actuated by a radially acting cam means which acts to move the mechanism radially inward to engage the plunger and to retain it in engagement with said plunger during forward movement of the plunger.

16. A device as claimed in claim 11 wherein the device is provided with means for positively acting on said plunger so as to prevent rearwards movement of said plunger at all times when a container is mounted on the device.

17. A device as claimed in claim 11 wherein said datum point is provided by a stop means against which a component selected from the drive mechanism and a part operatively associated therewith buts at the extreme of the forward travel of plunger on each of its incremental movements.

18. A device as claimed in claim 11 wherein there is provided a second stop means carried by said plunger which is engaged by a component selected from the drive mechanism and a part operatively asociated therewith as it is retracted, whereby the second stop member prevents the drive mechanism from being withdrawn to its full extent if the residual potential travel of the plunger is less than the desired dose.

19. A device as claimed in claim 11 having a container containing a medicament is mounted at its forward end.

* * * * *

US005554125A

United States Patent [19]

Reynolds

[11] Patent Number: 5,554,125

[45] Date of Patent: Sep. 10, 1996

[54] **PREFILLED VIAL SYRINGE**

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[21] Appl. No.: 245,132

[22] Filed: May 17, 1994

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 791,399, Nov. 16, 1991, Pat. No. 5,364,369, which is a continuation-in-part of Ser. No. 437,203, Nov. 16, 1989, Pat. No. 5,137,527, which is a continuation-in-part of Ser. No. 72,015, Jul. 8, 1987, Pat. No. 4,886,495.

[30] Foreign Application Priority Data

Nov. 14, 1990 [GB] United Kingdom 9024710
May 17, 1993 [GB] United Kingdom 9310084

[51] Int. Cl.[6] A61M 5/00

[52] U.S. Cl. 604/187; 604/200; 604/201; 604/203

[58] Field of Search 604/82, 87, 88, 604/89, 91, 92, 191, 187, 200, 201, 203, 204, 205, 411, 413, 414, 415, 416, 905, 232, 218, 220

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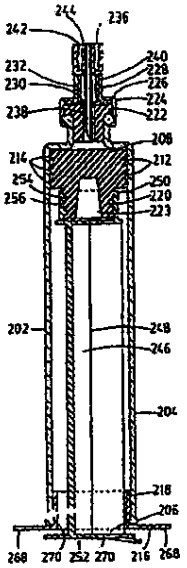
Primary Examiner—Corrine M. Maglione
Assistant Examiner—N. Kent Gring

[57] ABSTRACT

A prefilled syringe for one or two component medicaments is based upon the use of a vial containing a medicament or one component of a medicament, the vial having an open bottom closed by a piston. When a flexible extension of the piston is coupled with a tubular plunger, and an adaptor cap having an internal needle and an external connection for a needle is placed over a cap of the vial, the latter is converted into a prefilled syringe. The open bottom of the vial is configured so as not to interfere with handling of the vials by conventional vial sterilizing, filling and capping machinery, and may be formed so as to provide an internal shoulder which will secure a piston retention member.

14 Claims, 9 Drawing Sheets



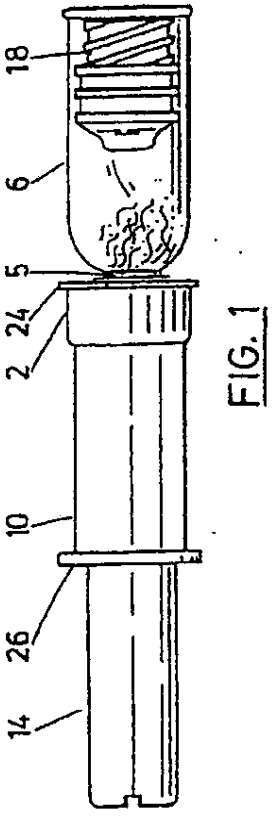


FIG. 1

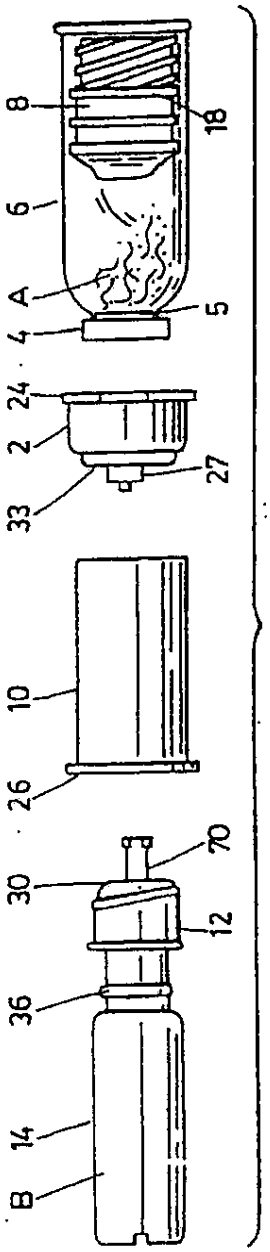


FIG. 2

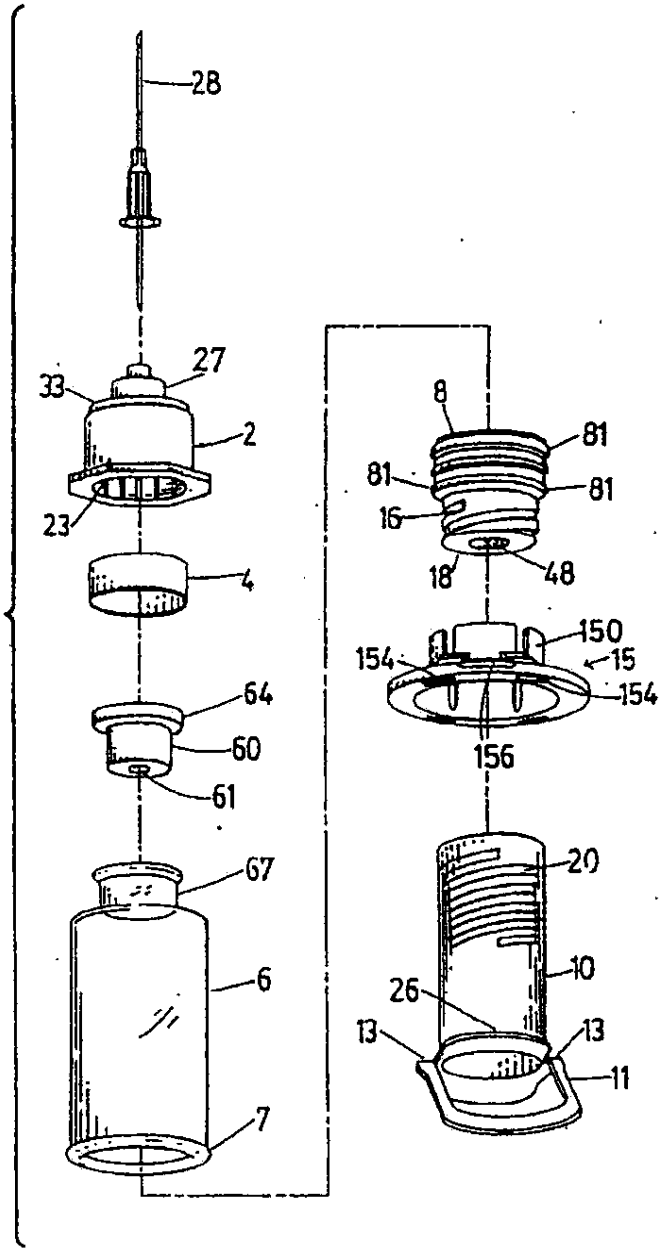

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FIG. 3

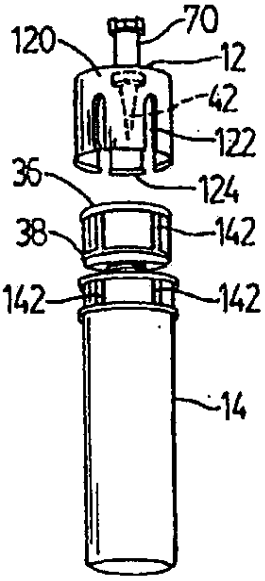
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FIG. 4

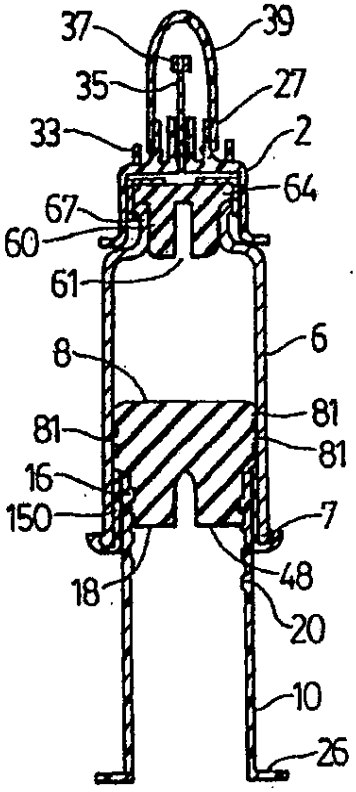
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FIG. 5

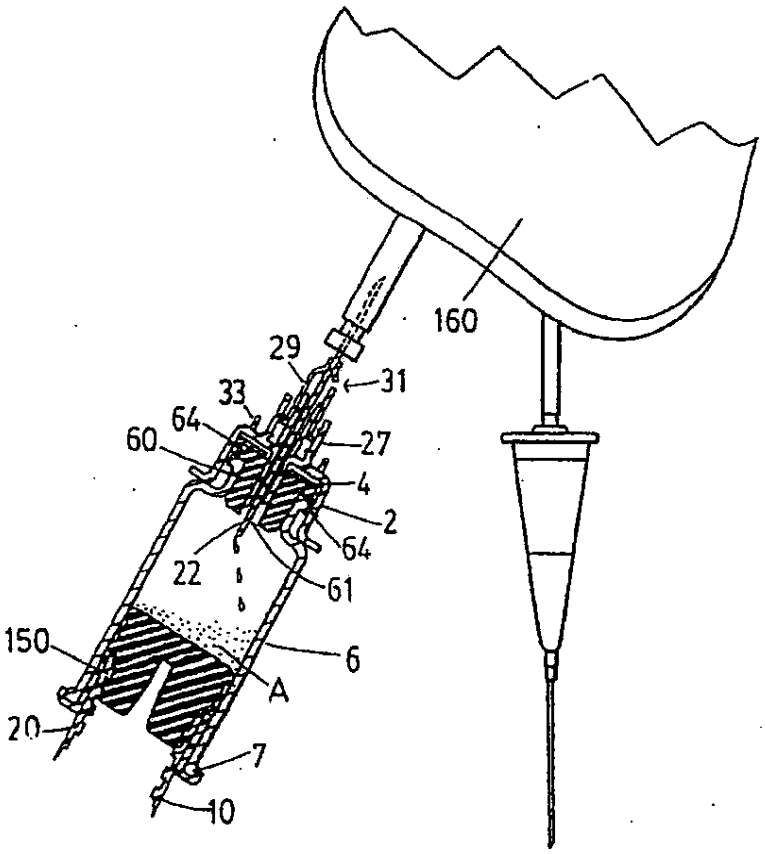

FIG. 6

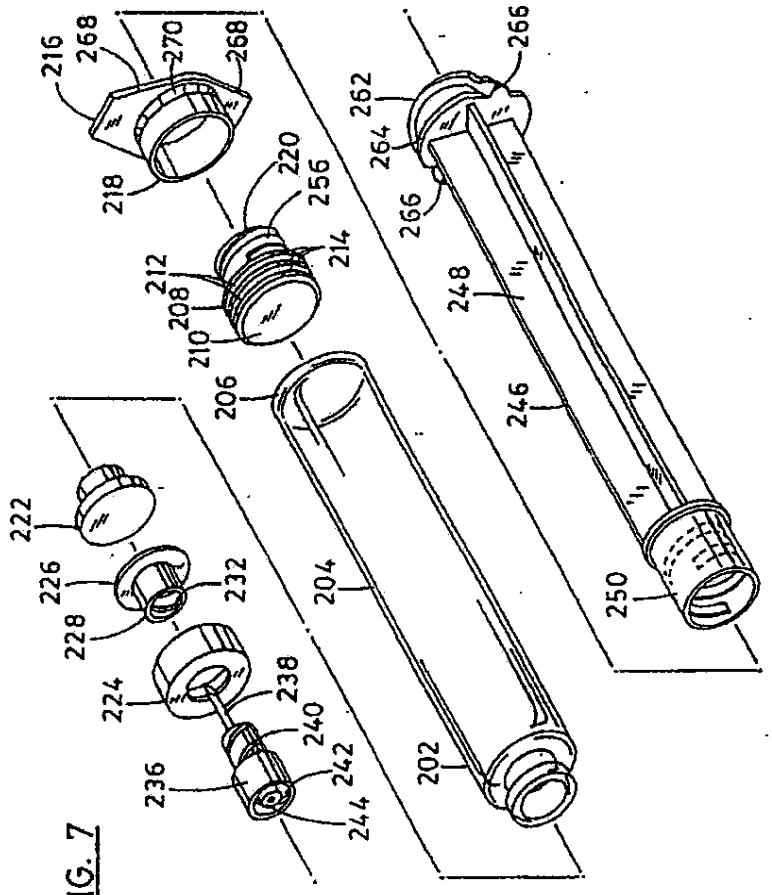
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FIG. 7

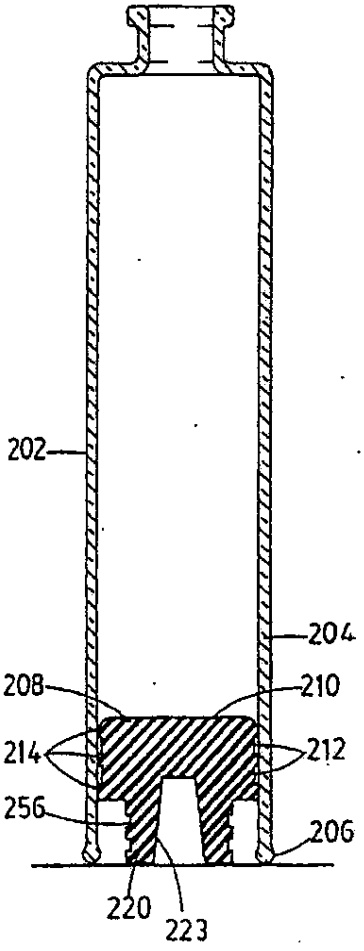
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FIG. 8

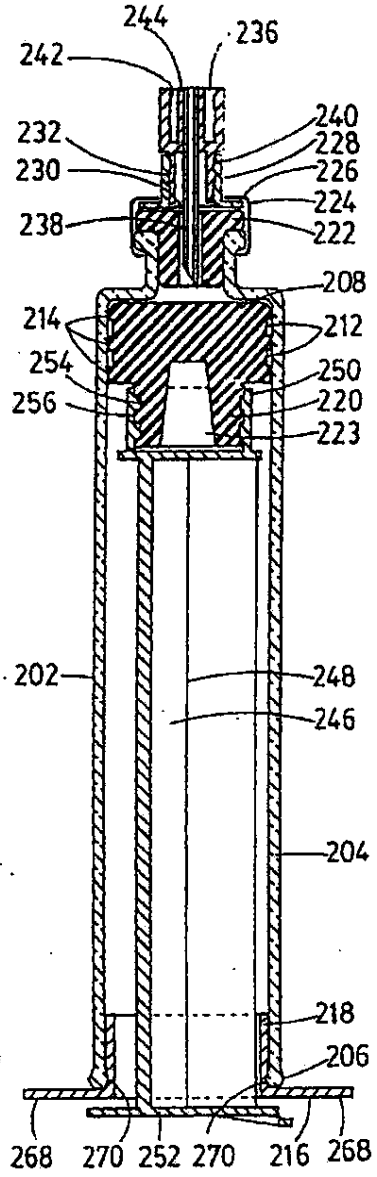
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FIG. 9

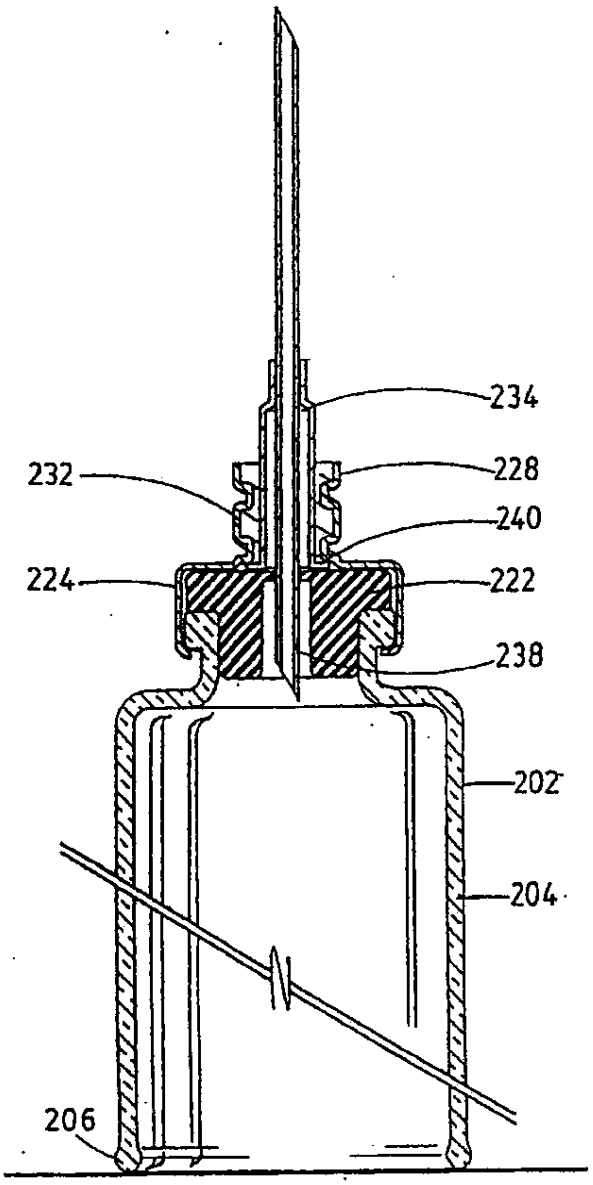


FIG. 10

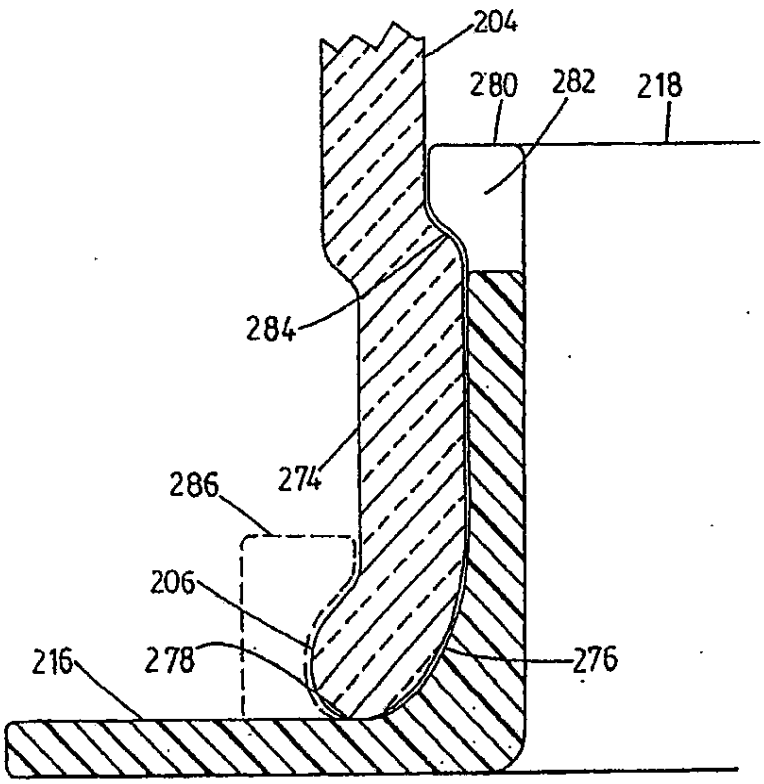


FIG. 11

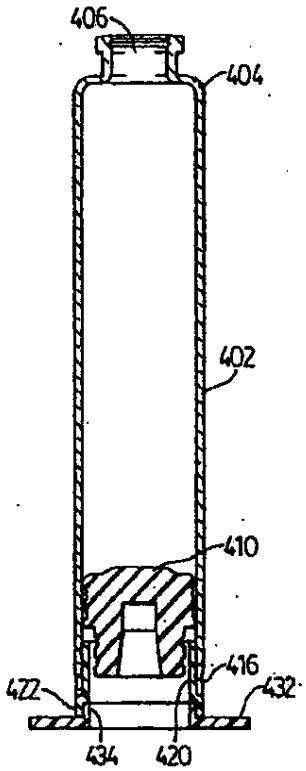
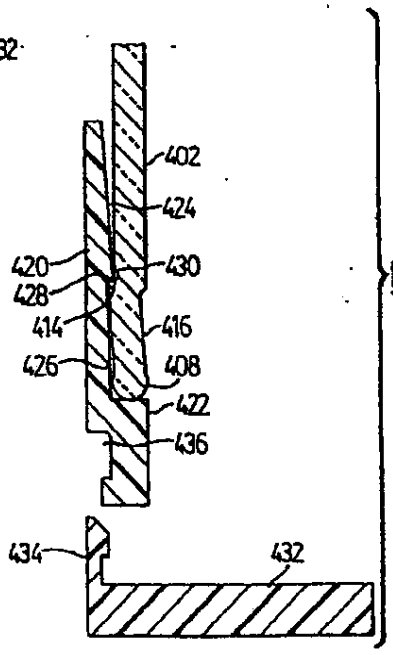

406
404
402
410
416
422
432
434
420

FIG. 12


402
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436
434
432

FIG. 13

PREFILLED VIAL SYRINGE

REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of my application Ser. No. 07/791,399 filed Nov. 16, 1991 now U.S. Pat. No. 5,364,369, which is a continuation-in-part of application Ser. No. 07/437,203 filed Nov. 16, 1989 now U.S. Pat. No. 5,137,527 which is a continuation-in-part of application Ser. No. 07/072,015 filed Jul. 8, 1987 and now U.S. Pat. No. 4,886,495.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to prefilled syringes for use in medical or veterinary treatment.

2. Review of the Art

There has been an increasing trend in recent years to the putting up of pharmaceuticals in dosage forms so as to minimize the preparation required to administer a medicament to a patient and to reduce the chances of dosage errors or contamination. One dosage form which has been gaining rapid acceptance is the prefilled disposable syringe. Various difficulties are however associated with the preparation and usage of such syringes, particularly in the case of preparations which, in ready to use condition, have a short shelf life. Numerous forms of dual compartment syringe structures have been proposed for the shipping of such preparations with components stored in separate compartments for admixture immediately prior to use. Although certain structures have met with some degree of acceptance, they are commonly difficult to manufacture and/or use because of difficulties in filling the syringe with the components, and because they require extensive manipulation immediately prior to use. Moreover they are frequently substantially more bulky than conventional syringes because in many cases they frequently comprise components which effectively represent two syringes in tandem.

Problems in the manufacture of prefilled syringes are not confined to two component systems and even with single component systems the filling of syringes under factory conditions is difficult to mechanize effectively and requires expensive special purpose syringe filling machinery. The same applies to related units prefilled with liquids required for injection or infusion during medical procedures.

Another approach where single component systems are involved is exemplified by British Patent Specifications Nos. 1,252,306 and 1,444,119, and U. S. Pat. No. 4,445,895, in which a prefilled cartridge having a displaceable plug at one end, and a needle penetrable closure at an opposite end, is inserted into the barrel of a syringe for dispensing of its contents. Whilst such cartridges and the equipment for filling them are known and available, they are only really suitable for preparations which can be stored in liquid form, and require either a special or a modified syringe for their use. The cartridges themselves require special filling apparatus.

In a further arrangement disclosed in U.S. Pat. No. 3,845,763, a cartridge or vial is closed at its bottom end by a slidable plug with a downwardly extending stem, which cartridge or vial is inserted bottom end first into a special holder which carries a double ended needle, so that the stem is penetrated by the needle and the body of the vial is converted into a plunger which can be depressed to expel the contents of the vial through the stem. The projecting stem

means that the vial cannot be filled utilizing conventional vial filling machinery.

The high capital expenditure involved in implementing known prefilled syringe systems has severely limited their adoption to those few cases where their advantages outweigh the substantial additional unit costs involved as compared to conventional modes of delivery.

SUMMARY OF THE INVENTION

The present invention seeks to provide a system for the distribution of preparations required for injection or infusion in liquid dosage form during medical procedures, which has a wide range of utility both for single component liquid preparations or for two component systems of which one component may be a solid, which utilizes a small number of components all suitable for mass production using material already approved for usage in such applications, which is simple to assemble and can be filled utilizing equipment already available to most pharmaceutical manufacturers, which minimizes the number of "clean room" operations required, and which minimizes certification problems.

The system is based upon and built around a basic component in the form of a 'bottomless vial'. Such a bottomless vial has all of the characteristics of a conventional pharmaceutical vial, except that the glass base of the vial is replaced by a piston wholly received within the vial and designed to form a hermetic seal with its cylindrical side wall, the seal being maintained both when coupled and when uncoupled from a plunger releasably connectable to the piston for moving the latter axially of the vial. A particularly important characteristic of such a bottomless vial is that it can be conveyed, filled and capped reliably by conventional vial sterilization, filling and handling equipment such as is already possessed by most pharmaceutical manufacturers. To this end, the bottomless vial must be free of features which would significantly compromise its stability when handled by such equipment. A flange or bead is required around the base of the vial for various reasons, but must result in no more than a slight increase in the overall diameter of the vial, and must be configured so as to avoid any substantial increase in its tendency to tip when jostled by other similar vials, and the centre of gravity of the vial must not be displaced so far upwardly as to substantially reduce the stability of the vial.

I have found that it is important that the bottom end of such a bottomless vial terminates in a somewhat rounded peripheral bead, which serves several purposes. Firstly, it strengthens the open end of the vial and reduces stress concentrations and the risk of breakage, particularly during insertion of the piston, as well avoiding the danger of glass particles chipping from the edge of the glass which arises in the absence of such rounding. Secondly, the rounding produces a slight internal flare which facilitates piston insertion. Thirdly, it provides means, if sufficiently pronounced, for securely engaging a subsequently applied piston retainer which prevents possible ejection of the piston during shipping and storage of the vial due to gas generation or expansion within the hermetically sealed vial above the piston.

Whilst the provision of a pronounced bead is thus highly desirable, conventional formation of the bead as an external projection on the body has the disadvantage of increasing the diameter of the bottom of the body, thus both increasing the capability of tipping of the vials while being conveyed, and possibly providing a ramp for such tripping by riding

over or under the beads of adjacent vials unless the external configuration of the bead is carefully controlled. At the same time, particularly for syringes prefilled with a single component liquid pharmaceutical, there may be a requirement for a syringe capacity which requires the height to diameter ratio of the body to be increased as much as possible, which in turn requires maximum stability of the vial when conveyed free-standing.

The piston must be capable of maintaining a hermetic seal with the wall of the vial, of integrity comparable to that achieved during capping of a conventional vial, and this seal should be maintained in storage and during manipulation of a syringe system incorporating the vial, during which the piston may be subject to non-axial forces transmitted to it by a plunger and tending to break the seal.

In the context of the invention, it should be understood that "vial" refers to a particular type of container, having a rather squat cylindrical body whose height compared to the diameter of its base is such that it may stand stably on its base whilst being conveyed through a vial handling and filling machinery and whilst subsequently sealed and capped. Its body should also be free of external projections large enough to interact with other vials or the filling machinery in a manner such as to promote tipping. A vial has a neck with a large enough internal diameter to permit filling from a vial filling machine: solid filling materials will normally require a larger neck than liquids. Vials should not be confused with cartridges, which are comparatively long and slim, and cannot usually be filled utilizing vial filling machinery since they are too tall to rest in a stable manner on their bases. Cartridges also are typically thin-walled and lack a bead or flange, which renders them fragile, and makes it difficult to insert a piston without excessive risk of breakage.

The differences between such vials and a conventional vial do not prevent them from being filled and capped in conventional vial filling and capping machinery; indeed, apart from the replacement of the bottom wall of the vial by a piston as specified, it is a conventional vial, and can be handled normally by the machinery during filling with either liquid or solid material. The presence of the piston, which is relatively massive, in the lower part of the vial even helps stabilize the latter during filling. Obviously the cubic capacity of such a vial is less than the capacity of a conventional vial of comparable overall dimensions but for most purposes this is immaterial.

The invention provides in one aspect a pharmaceutical vial used for forming a barrel and a piston of a syringe after being filled and capped, comprising a cylindrical glass vial body having at one end an integral open neck and a peripheral external flange around an outer end of the neck, a peripheral rounded edge defining an inner periphery of an open opposite end, and a piston of resilient material having a cylindrical head within and concentric with the cylindrical glass body, the piston maintaining a slidable hermetically sealing relationship with a main inner cylindrical surface of the body, and being located to define a chamber of volume equal to the nominal capacity of the vial between the piston head and the neck of the vial, the piston having integral coupling structure wholly within the body for subsequent connection to a syringe plunger, and the vial being stable when standing on the open end of the body such that it can be conveyed while so standing through vial filling and capping machinery without tipping over, the body being formed adjacent said open end with peripheral radially extending positive retention means for engagement with complementary configurations of a tubular piston retaining member subsequently inserted within said open end of the body to resist overpressure within the body, wherein the retention means is formed by shaping a lower end portion of the body to have a reduced internal diameter such that the retention means is formed by an upwardly facing shoulder at the top of the lower end portion which projects inwardly of the projected circumference of said main interior cylindrical surface, and the lower end portion is located essentially within the projected circumference of a main cylindrical external surface of the body such as to leave the external surface of the body free of projections having an adverse effect on the stability of the vial.

A vial in accordance with the invention may be converted into a syringe by the addition of a plunger coupled to the piston and an outer cap which acts as a needle carrier. More specifically, the syringe includes as well as the vial a syringe plunger connected to the flexible extension from the piston, and an outer cap engaged over the cap of the vial, the outer cap having a hollow needle projecting axially within the cap and a coupling for engagement with injection means and communicating with said hollow needle, the outer cap being axially movable relative to said cap of the vial from a position in which the needle ends short of the cap of the vial to a position in which it penetrates the cap of the vial. The plunger is provided with radially extending flanges for sustaining actuating forces applied to the syringe through a flange grip provided on the outer cap or on a plunger guide or piston stabilizer ring applied to the open end of the vial.

In a syringe for a two component medicament, it is necessary to provide for packaging of the second component and its admixture with the first component in the vial prior to dispensing. The invention thus further extends to a capsule assembly comprising a generally cylindrical sealed capsule having walls formed of a flexible needle penetrable material of suitable properties, a generally cylindrical neck defined by said walls at one end of the capsule, said neck having axially spaced inner and outer peripheral ridges, and a generally cylindrical cap applied to said neck so that a detent within the cap engages the outer peripheral ridge on the neck, a hollow cannula being formed integral with and passing through said cap so that an inner penetrating end within the cap ends short of the neck of the capsule and an outer end in the form of a fluid coupling which extends outwardly of the cap, the cap being displaceable relative to the capsule to a position in which the detent rides over the inner ridge and the inner end of the needle penetrates the neck of the capsule, the cap and capsule being of a diameter such that they can enter the tubular plunger to a position in which a coupling at the outer end of the cannula, is connected to the coupling on the outer cap of the syringe, with the plunger being used as a support for the capsule prior to being coupled to the piston.

Thus the injection system comprises a sequence of components of which various sub-sequences can be combined to form injection systems for preparations requiring shipping and storage as two separate components, certain sub-sequences themselves having utility respectively as injection systems for single component liquid preparations. "Injection" is utilized broadly to cover hypodermic, intramuscular and intravenous injection, gravity and mechanical infusion, and injection into other vessels utilized in medical treatment or testing. For the purposes of description, the "front" or "top" end of an injection system will be considered the end of the system from which a liquid preparation is so injected.

The invention also provides, in a method of producing a prefilled syringe for administering a pharmaceutical preparation, said syringe comprising a generally cylindrical

syringe body having a neck at one end and a side wall having a bead finish at the other end, at least a component of the preparation filled into said body, an elastomeric closure closing the body at the neck end and secured by a cap, and an elastomeric piston at said other end forming a hermetic seal with an inside surface of said side wall, needle means for movement relative to the cap to penetrate the elastomeric closure, and plunger means for connection to an outer side of the piston, the improvement wherein the syringe is produced by associating components, including said plunger and said needle, with a prefilled vial produced by forming said body with height to diameter ratio such that the body is stable, and so that any outward extent of the bead is insufficient to result in interference such as would cause tipping, when the body is conveyed standing on said other end through equipment for filling and capping pharmaceutical vials, inserting said elastomeric piston wholly within said other end of the body to form a vial open at the neck, and filling said vial through said neck with said pharmaceutical preparation component, and then applying said elastomeric closure on said cap, whilst conveying the vial standing on said other end through equipment for filling and capping pharmaceutical vials.

Further features of the invention will become apparent from the following description of preferred embodiments thereof with reference to the accompanying drawings.

SHORT DESCRIPTION OF THE DRAWINGS

FIGS. 1 and 2 are elevational and exploded views of a first embodiment of the syringe system;

FIG. 3 shows the separated parts of a modified embodiment of the syringe system;

FIG. 4 shows, separated, a diluent capsule and cap for use with the system of FIGS. 1 and 2 or 3;

FIG. 5 is a longitudinal cross section through the assembled system of FIGS. 3 and 4;

FIG. 6 is a fragmentary view of a syringe in accordance with the invention utilized in conjunction with an I.V. bag;

FIG. 7 is an exploded isometric view of the components of a further embodiment of syringe;

FIG. 8 is a vertical section through a vial portion of the syringe of FIG. 7, ready for filling;

FIG. 9 is a longitudinal section through an assembled syringe, after discharge of its contents;

FIG. 10 is a fragmentary longitudinal section on an enlarged scale of a portion of the syringe shown in FIG. 9, showing a modification of the arrangement shown in that Figure; and

FIG. 11 is an enlarged vertical section through the bead of a modified embodiment of the syringe, also showing adjacent parts of a modified piston retainer and finger grip.

FIG. 12 is a longitudinal section through the body of a further embodiment of bottomless vial, shown fitted with a piston retainer ring;

FIG. 13 is a detail of the body and retainer ring shown in FIG. 12, on an enlarged scale;

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIGS. 1 and 2, a syringe system for the injection of a liquid preparation stored as two components comprises seven primary mechanical components, apart from the components of the preparation. The components of the preparation typically comprise a first component A which may be in any physical state suitable for storage in vial, and a second liquid component B, typically but not necessarily sterile water. The liquid component B is stored in a sealed capsule 14 of flexible material, manufactured using conventional techniques from a material, usually synthetic plastic, which is compatible with the contents of the capsule. The first component is stored in a cylindrical vial 6, typically of glass, and capped by an annular cap 4 which retains a conventional needle penetrable sealing member accessible through a central opening in the cap. By a vial is meant a cylindrical vessel which can assume a stable upright position supported by its base, the overall height of the vessel exceeding the external diameter of the rim of its base by a factor sufficiently small that it remains stable when passing through conventional vial filling and capping equipment utilized to fill and cap the vial. This factor preferably does not exceed 2.5 for the present embodiment, but can be increased by means discussed further with reference to FIGS. 7–13. A neck 5 at the upper end of the vial 6, which is capped by the cap 4, has a relatively internal diameter characteristic of such vessels, usually not less than about 7.5 mm for liquid or 10 mm for solids, so that filling with either liquids or solids can be readily achieved. The cap 4 is formed by an aluminum sleeve, having a flange retaining a sealing member formed by a soft rubber disc or plug 5 over or in the front end opening, and tightly crimped onto a neck at the front end of the vial so as to seal the latter. A major difference from conventional vials is that the conventional bottom wall of the vial is replaced by an axially movable piston 8 wholly within the vial and in sealing contact with the vial walls. When received within the vial 6, this piston in no way interferes with the handling of the vial using conventional machinery, and in particular permits the vial to be stood on its base with its neck (5) (which forms the front end of the vial when in use) upwards as it passes through the filling and capping equipment.

The filled vial 6 may be converted into a prefilled syringe by applying an outer cap 2 over the cap 4 and positively attaching a cylindrical plunger sleeve 10 to the piston 8. The piston 8, typically formed of rubber, is moulded with a rearward extension 16 with an external thread 18, while the interior of the front end of the plunger sleeve 10 is formed with a complementary internal thread 20 (see FIG. 3) so that it may be screwed onto the piston 8. A recess 48 (see FIG. 3) may be formed in the extension 16 to increase its flexibility. The outer cap 2 fits over the inner cap 4 so that a hollow needle 22 (see FIG. 6) formed within the cap 2 does not reach the penetrable zone of the cap 4. On the front of the cap 2 and in communication with the hollow needle 2 is a coupling adapter 27, for example similar to those sold under the trade mark LUER-LOK, for connection of the syringe to a needle 28 or other instrumentality (see FIG. 3). To prepare the syringe for use, the outer cap 2 is pulled back over the inner cap 4 so that the needle 22 penetrates the cap, and the needle 28 or other instrumentality is applied. This should be done without pressing on the plunger sleeve so as to avoid accidental ejection of the contents of the syringe. The rear ends of both cap 2 and the sleeve 10 are formed with radially extending flanges 24 and 26 respectively which form finger grips for operation of the syringe. Thus if a user grips the assembled syringe by the flanges and presses them towards each other, the contents of the syringe can be expelled through the needle 22 and the needle 28. It will be noted that the rear end of the vial 6 is formed with only a relatively slight external bead 7 rather than the wide finger flange commonly found on the barrels of conventional

syringes. In the present arrangement, the flange 24 provides the function of such a finger flange, enabling the bead 7 to be reduced to a size which will avoid such interference between the flanges of adjacent vials as would cause tipping when the vials are conveyed in a vertical attitude through filling and capping equipment.

In many applications, it is desirable to prevent premature penetration of the plug 5 by the needle 22, and therefore the cap 2 may be moulded with short internal threads (not shown) which prevent rearward movement of the cap 2 unless it is twisted so that the threads bite into the soft aluminum of the cap 4 and draw the cap 2 rearwardly so that the needle 22 can penetrate the plug.

A prefilled syringe constructed as discussed above has significant advantages over conventional prefilled syringes in that the vial may be filled using conventional vial filling equipment, and yet may be utilized directly instead of requiring its contents to be transferred to a syringe prior to use as has been conventional in the use of vials.

The vial may also be charged with material which is not directly injectable, such as solids which must be dissolved or suspended in a liquid medium prior to injection. In this case the liquid medium is sealed as already described in a flexible capsule 14. A third cap 12 is applied to the capsule as shown in FIG. 2, which is inserted into the plunger sleeve 10 so that a screw thread 38 on the exterior of the cap engages screw thread 20 within the sleeve.

A neck 34 of the capsule 14 (see FIG. 4) has two peripheral ridges 36 and 38. As the cap 12 is applied to the capsule, a detent 40 within the cap is pushed over only the outer ridge 38 so that a hollow needle 42 mounted in the cap stops short of the end of the capsule. By forcing the detent 40 rearwardly over the ridge 36, the needle 42 can be forced rearwardly so as to penetrate the capsule.

The conduit in the needle 42 extends through the cap 12 into an extension 70 which is configured at its outer end to couple with a standard syringe coupling such as the coupling 27 on the cap 2. This enables the capsule 14, once inserted in the plunger 10, to be locked through the extension 70 and the coupling 27 to the cap 2 to produce the compact assembly shown in FIG. 1. The inner end of the plunger 10 is a press fit on an annular retaining flange 33 formed on the cap 2. To prepare the syringe for use, the cap 2 is forced rearwardly over the cap 4 so that the needle 22 within the cap 2 pierces the seal 5, and the capsule 14 is forced forward so that it is pierced by the needle 42 and its contents can be expelled through the needle 42, the extension 70, the coupling 27 and the needle 22 into the vial 6. The assembly of the capsule 14 and the plunger 10 can then be released from the remainder of the syringe by turning so as to release the extension 70 from the coupling 27, a needle (see FIG. 3) may be applied to the coupling 27, the capsule 14 is removed from the plunger 11 and discarded, and the plunger 11 is screwed onto the coupling 18 to ready the syringe for use.

A similar arrangement may be utilized for single component medicaments in which case the capsule 14 and cap 12 are not provided. The arrangement is advantageous for both single and multiple component medicaments since only the vial need be assembled and filled in a clean room, the only additional step required over the filling of a conventional vial being the insertion of the piston 8. The plunger 10 may be pressed onto the cap 2, and this assembly, if desired together with a needle and/or a capsule 12 and cap 14, may be separately sterilized and packaged, without endangering the stability or destroying the contents of the vial, which will often be sensitive to heat or radiation utilized for sterilization purposes. Since the capsule 12 can withstand conventional terminal sterilization techniques (see further below), it can be sterilized independently of the vial. This is a major advantage over many two-component syringe systems in which the components are separated only by some form of penetrable plug or diaphragm and must therefore either be fully assembled in a clean room, or subjected to assembled form to terminal sterilization techniques which may destroy or damage a component of the pharmaceutical preparation.

Where the capsule 12 is not being used, it is possible to utilize a cap 2 in which the needle 22 is not provided, and instead use a needle arrangement as shown in FIG. 3 or FIG. 5.

Further features of the invention are shown in FIGS. 3-5. The same reference numerals are used to denote the same parts in these figures as in the previous figures, where applicable, and construction and operation are similar except where otherwise indicated.

FIGS. 3-5 show a vial and syringe system according to the invention, the vial comprising a body 6 of rigid transparent material, usually glass although synthetic plastic resins might be utilized in certain applications. The body has the general configuration of a conventional vial except for the absence of a bottom wall. In order to compensate for the strengthening effect which would be provided by the bottom wall, in order to provide a detent for an optional plunger stabilizer ring 15 described further below, and in order to permit a slight flare at the extreme bottom end of the vial, a rounded bead 7 is provided around the perimeter of the bottom end of the body, although its peripheral extent should not be sufficient to increase substantially the diameter of the vial or decrease substantially its stability during handling.

A medicament A is retained within the vial by a piston 8. A closure 60 substantially fills a neck portion 67 of the vial after the vial, closed at the bottom by the piston, has been filled through its neck portion by a conventional vial filling machine. Although the medicament shown is a solid, it may be a liquid, or filled as a liquid and lyophilized to leave a solid residue. The piston 8 is moulded from rubber, preferably of at least 50 durometer hardness, and is formed with multiple, preferable three, peripheral ribs 81 on its outer surface, the external diameter of the ribs being slightly greater than the internal diameter of the body 6 so that an hermetic seal is established when the piston is pressed into the bottom of the body, initial entry being assisted by the flare mentioned above. The piston is moulded as a substantially solid body so that it has sufficient rigidity to maintain the desired hermetic seal with the body, any central bores within the piston (see FIG. 5) required to assist needle penetration being of insufficient radial extent to have any significant effect on its rigidity. Although in the piston shown in FIG. 6, a central bore 48 does just extend into the piston proper, its axial extent within the piston and its diameter are sufficiently small relative to the piston diameter that the rigidity of the piston is not substantially reduced.

The piston has a downward extension 18 of reduced diameter, in which the bore 48 is also present. The diameter of the bore 48 forms in this case a greater portion of the diameter of the extension 18, whose flexibility is thus somewhat increased by its presence. The extension carries on its outer surface a multistart thread, defined by grooves 16 which terminate abruptly short of the piston, forming abutments serving a purpose discussed further below. Provided that the hardness and rigidity requirements for the piston as a whole are met, the rubber utilized to form the piston, and any external coating on the rubber (which may

act to increase the effective hardness of the rubber), are selected for compatibility with the medicament contained in the syringe, a number of approved materials being available and well known in the pharmaceutical art.

The neck closure 60 may be formed of similar rubber. After insertion of the closure 60, its flange 64 may be held in place by a conventional cap 4 crimped over the flange and a flange on the neck of the bottle. Such a cap 4 may have a flip-off top attached to a separable central portion of the cap, partially severed from the remainder of the cap so that these portions may be broken away prior to assembly of the syringe to expose a central needle penetrable zone of the closure 60 above the bore 61.

The piston together with its extension 18 is relatively massive, with a weight which typically amounts to at least a major portion of that of the body 6. This weight in the lower part of the body assists in stabilising the vial during handling and filling and further inhibits tipping.

As mentioned above, vial assembly and filling will normally be performed in a clean room, since many pharmaceuticals will not withstand terminal sterilization procedures. The only additional step which requires to be carried out in the clean room other than is conventional in the filling of vials is the insertion of the piston 8.

In order to convert the basic vial into a syringe system, the procedure described with reference to FIGS. 1 and 2 may be used. Only the differences will be described in detail for this embodiment. FIG. 3 shows the components of a syringe system separated, while FIG. 5 shows them assembled and sectioned (although an alternative needle arrangement is shown in FIG. 5). It should be understood that the diluent cartridge 14 and cartridge cap 12 as shown in FIG. 4 are optional features of the system and will only be utilized when a diluent or solvent is required for the content of the vial which is not provided by some other means.

Referring to FIGS. 3 and 5, an outer cap 2 is pushed over the cap 4, and is similar to that shown in FIG. 2, except that the internal needle 22 shown in FIG. 6 is omitted, the syringe being utilized with an alternative needle arrangement. In FIG. 13, a conventional double ended needle 28, is shown, the inner end of which replaces the needle 22.

FIG. 5 shows an arrangement in which the needle 28 may be single ended, an auxiliary hollow needle 35 being provided with a cylindrical sleeve 37 at the top which replaces the outer extremity of the inner portion of the coupling 27. A cap 39 is provided to retain the needle 35 within the coupling 27 until the needle 28 is fitted. When the syringe is to be used, the cap 39 is removed, and the sleeve of the needle is placed over the sleeve 37 and pushed down so that the needle 35 can penetrate the top of the vial and the needle 28 can be engaged with the coupling 27.

These needle arrangements are preferred for a syringe which is shipped in an essentially ready-to-use form, since the cap 2 may be pushed fully onto the cap 4 during assembly, yet the closure 60 remains unpenetrated until the needle (or other instrumentality as discussed below) is fitted at the time of use. On the other hand, the integral needle 22 is convenient where the assembly is to be utilized in the manner shown in FIGS. 1 and 2 and a capsule 12 is utilized. The inner surface of the cap 2 is provided with longitudinal ribs 23 which indent the soft aluminum of which the cap 4 is typically fabricated, and help retain the cap 2. The portions 41 and 43 of the cap 4, if present, are of course broken away prior to application of the cap 2.

The cap 4, closure 60, vial body 6 and piston 8 have already been described in detail above. The plunger 10 differs from that shown in FIGS. 1 and 2 in two respects. Its internal threads 20 end abruptly at abutments short of the front end of the plunger, so that when the plunger is screwed onto the extension of the piston, the abutments at the ends of the threads meet abutments at the ends of the external grooves on the extension which grooves in this embodiment stop short of the inner end of the extension, just before the inner end of the plunger contacts the rear surface of the piston. This prevents the plunger being screwed excessively tightly against the back of the piston in a manner which might result in rocking movements of the plunger being transmitted directly to the piston. Instead such movements are largely absorbed by the flexibility of the extension 18. Secondly, the flange 26 at the rear end of the plunger is moulded so that about one half of its periphery is separated into an integral loop 11, which can be flexed rearwardly about hinge lines 13, and serves either as a thumb loop to assist manipulation of the syringe, or a suspension loop from which the syringe can be hung during infusion of its contents as discussed further below. The synthetic plastic material from which the plunger is moulded is selected from those having hinge forming capability such as many pharmaceutically acceptable grades of polypropylene.

In order to provide further stabilization of the plunger, to prevent its withdrawal from the body, and to provide a finger grip during manipulation of the syringe, particularly where longer vial bodies 6 are utilized, an optional plunger stabilizer and adapter ring 15 may be provided. This has axially extending inner flanges 150 which enter the inner end of the body, and retaining lugs 152, which snap over the bead 7. Openings 154 and flanges 156 may be provided on the rear surface of the ring, as required, to assist in adapting the syringe to infuser apparatus.

Where the contents of the vial are liquid and do not require reconstitution or dilution, or reconstitution is effected by a diluent or solvent introduced via a needle or cannula through the closure 60, the cartridge cap 12 and diluent cartridge 14 are not required, the components already described constituting a complete syringe system. Otherwise these components may be provided and utilized as already described in relation to the embodiment of FIGS. 1 and 2. The components themselves are however somewhat modified as shown in FIG. 4, to facilitate handling. A skirt portion 120 of the cap is formed with longitudinal slots 122 extending from its rear edge, and inner lips 124 around the inner periphery of that edge, whilst a front extension of the cartridge 14 is provided with ribs 142 extending longitudinally between the peripheral ridges 36 and 38, which ribs are accommodated by the slots 122. The ribs 142 are continued beyond a peripheral groove behind the ridge 36. The threads 30 and the cap 12 are reduced to short ridges between certain of the slots 122. Because of the slots, the cap 12 is readily engaged over the ridge 38, but when the assembly is inserted into the interior of the plunger 10, the diameter of the cap relative to the internal chamber of the plunger 13 such that the lip 124 is pressed into the ring of shallow recesses defined between the ridges 36 and 38 and the ribs 142, thus ensuring that the threads 30 may be engaged with the threads 20 within the plunger by turning the capsule, and inhibiting accidental forward movement of the cartridge 14 into the cap 12.

The capsule 14 is blow moulded from a heat sealable, film grade, low melting, high ethylene random propylene-ethylene copolymer suitable for medical use. An example of such a material, already approved for pharmaceutical applications, is DYPRO (trade mark) polypropylene Z9350 from Fina Oil and Chemical Company which has a melting point

of about 130° C. Such a material, formed by injection of ethylene into a propylene matrix, combines necessary qualities of transparency, impermeability and flexibility with the stability to withstand sterilizing temperatures in an autoclave, despite its low melting point; the pressure in the autoclave is maintained at a sufficient level to prevent bursting of the capsule during sterilization. Conventional capsule materials are unsuitable for use in this application, since they lack at least one of the necessary properties of flexibility, transparency, impermeability, penetrability, compatibility with conventional pharmaceutical diluents, and ability to withstand sterilization temperatures without failure or degradation.

Utilization of syringes incorporating the above described modifications is similar to that already described. With a small modification to certain of the syringe components, the syringe contents may be reconstituted or diluted with fluid from an I.V. bag or minibag 160 and then injected into the bag for delivery, as shown in FIG. 6. Both the inner and outer components of coupling adaptor 27 of the cap 2 are elongated, and the bores of the inner component of the coupling adaptor and of the needle 22 are sufficient to provide an air venting passage around the read end of the needle 22 when fitted to the adaptor 27. A locking sleeve 29 on the needle 22, which sleeve engages the adaptor 27, is provided with a ventilation opening 31, such that when the sleeve 29 is screwed partially onto the adaptor as shown, air can escape through the sleeve as fluid from the bag 160 enters the syringe through the needle 22. When a desired amount of fluid has entered the syringe, the ventilation opening is closed by screwing the needle further onto the adaptor, following which the contents of the syringe may be injected into the bag 160.

Referring to FIGS. 7–10 of the drawings, a syringe comprises a syringe barrel in the form of a somewhat elongated glass vial 202, of which the bottom wall is absent apart from a slight inward projection of a strengthening bead 206 formed at the bottom of a side wall 204 of the vial and best seen in FIG. 20. In the example shown the strengthening bead 206 also has a very slight outward projection, but this is far smaller than would be necessary if the bead were formed wholly externally of the side wall 204, and may be entirely eliminated. In any event, the outward extent of the projection should be insufficient to prevent vials from standing very closely adjacent to one another without sufficient space to tip. Typically the projection will not exceed about one fifth of the total thickness of the bead. The projection of the bead on the inside should also be limited, both so that the bead 210 of la moulded rubber piston 208 can be inserted into the vial past the projection (this is facilitated by the presence of peripheral grooves 212 in the bead between sealing lands 214), and so that a sleeve 218 of a combined finger grip, piston stop and plunger guide 216 (henceforth referred to as the finger grip) can be pushed past the projection whilst remaining a snug fit within the side wall of the vial. Insertion is facilitated by the slight flare provided at the bottom entry to the vial body by the rounding of the bead, and the insertion is readily mechanized.

The piston 208 is also provided with an integrally moulded downward extension 220 which is formed with a central cavity 223 to increase its flexibility relative to the head 210 of the piston which is substantially solid. The piston is dimensioned so that when it is inserted in the vial 202, the lands 214 are compressed sufficiently to form a hermetic seal against the interior of wall 204 whilst permitting the piston to be moved longitudinally of the vial. Initially, the piston is located at the bottom of the vial (see FIG. 8), with the bottom of extension 220 just within the vial so that it does not affect the ability of the vial to stand upright on its base formed by the bead 206. The location of the fairly massive solid rubber piston 208 at the base of the vial helps stabilize the empty vial 202, even when the height of the latter is somewhat greater relative to its diameter than is normally required for stability. The practical limit of the height to diameter ratio is set entirely by the requirement that the vials can be conveyed through a conventional vial filling and capping machine in a sufficient stable manner to permit reliable operation of the machine. In the example shown, the vial has an outside diameter of approximately 3 cm and a height of 12.8 cm for this diameter. A height of 14 centimeters is believed to approach the practical limit for stability, but this ratio will vary somewhat according to the relative wall thickness of the vial and the weight of the piston. Provided that the outward projection of the bead 206 is insufficient to affect stability, so that the vials can jostle without applying tipping force to each other, and assuming use of a piston generally as described, the maximum ratio attainable should be greater than 4, but will be less than 5.

The stopper 222 and cap 224 applied by the conventional vial filling and capping machinery may be of conventional construction, although the stopper 222 is preferably designed substantially to fill the neck of the vial so as to minimize dead space above the piston when the latter is pushed to the top of the vial (see FIG. 9). This ensures that as much as possible of the contents of a syringe formed from the vial can be expelled by movement of the piston.

The cap 224 is preferably modified as shown in FIG. 9 and FIG. 10. In FIG. 9, a conventional main cap cooperates with a moulded plastic adaptor assembly comprising an annular flange 226 within the cap, a cylindrical extension 228 extending through the cap and a thin diaphragm 230 closing a bottom end of the extension. An internal thread 232, similar to that provided on conventional syringe adaptors for receiving needles, such as those sold under the trade-mark LUER-LOK, is formed within the adaptor. A removable push on cap may be provided to close the open end of the adaptor during storage, being removed prior to use. In FIG. 10, the cylindrical extension 228 is formed integrally with the aluminum cap, again with an internal thread 232. I have found that the extension 228 can be accommodated by conventional vial capping machinery, at any rate with no more than minor modification, without interfering with the capping process, whilst the provision of such an extension enables the elimination of a separate adaptor cap, and the additional assembly step required to apply it.

In order to convert the vial into a syringe, either a double ended needle 234 of the blood collecting type may be applied directly to the extension 228 (see FIG. 10) or an adaptor 236 (see FIGS. 7 and 9) may be provided for any needle or alternative delivery device equipped with a standard syringe coupling so as to provide the latter with the capability of penetrating the stopper 222, as well as the diaphragm 230 if present. The adaptor 236 has a needle 238 and external thread 240 at one end, the needle providing the penetration function and the thread 240 engaging the thread 232, while its other end provides an internally threaded socket 242 and coaxial spigot 244 for forming a fluid-tight coupling to the needle or the like.

Prior to fitting the double ended needle 234, or needle and adaptor 236, a plunger 246 is applied to the extension 220 of the piston. The plunger has a shaft 248, of cruciform cross-section in the example shown, an internally threaded sleeve 250 at its one end, and an end flange 252 at its other end. The sleeve 250 has internal multistart threads 254,

complementary to external multistart threads 256 on the extension 220. The lands between the threads 254 on the sleeve 250 and the threads 256 on the extension 220 both stop short respectively of the outer end of the sleeve 250 and the inner end of the extension 220 so as to form abutments 258, 260 which prevent the sleeve 250 from being screwed tightly against the underside of the head 210 of the piston. This means that any tilting forces applied to the plunger are applied to the relatively flexible extension 220 and not directly to the head 210, thus minimizing the risk of breaking the hermetic seal between the head 210 and the vial.

The plunger is formed of a hinge-forming synthetic plastic such as a pharmaceutical grade polypropylene, and a generally semicircular peripheral portion 262 of the flange and is separated from the remainder of a slot 264, remaining connected only by thin, hinge-forming connections 266. This portion 262 provides a finger loop which can be pulled rearwardly, as shown by broken lines in FIG. 1, to facilitate handling of the plunger. As a supplemental or alternative feature, a notch 272 may be formed in the shaft 248 of the plunger, to provide a hook by means of which the syringe may be suspended when used in certain infusion applications.

In order to provide the various functions of preventing total withdrawal of the piston, forming a guide for the plunger and restricting its tilting movements, and providing a finger grip for the user, the combined finger grip and retainer 216 is pressed into the bottom of the vial 202 after filling and capping of the latter. It comprises the sleeve 218 and a peripheral flange forming oppositely extending finger grips 268. It is also moulded from a pharmaceutical grade of plastic such as polypropylene. The sleeve 218 is a resilient press fit in the open end of the vial 204 so that it is slightly compressed by the internal projection of the bead 206 during insertion. Insertion of the retainer 216 may be facilitated by moderate warming of at least the retainer, and the slight flare provided by the rounding of the bead 206 also facilitates insertion. Beneath the grips 268 the sleeve has shallow arcuate grooves 270 in which the bead 206 snaps as the sleeve is pressed home. Forces applied to the grips 268 tending to pull the sleeve 218 away from the vial in turn tend to deform the sleeve, in such a manner as to increase the grip of the grooves 2700 on the bead thus resisting withdrawal of the sleeve.

During manufacture, the empty vials 204 are conveyed through a conventional sterilizing station, the piston 208 is inserted in each vial 204, and the latter is filled and capped utilizing conventional vial filling and capping machinery (but preferably using a modified cap as shown in FIGS. 7 and 9 or FIG. 10). The guide and finger grip 218 is then pressed into the base of the vial, which is shipped with the plunger 246 unattached. Prior to use, the plunger 246 is screwed onto the piston, and a needle or the like is applied to the extension 228, utilizing an adapter 236 if necessary so as to penetrate the stopper 222, at which point the syringe is ready for use.

A modified configuration of the bottom end of the vial body is shown in FIG. 11, in which an alternative approach is utilized to bringing the bead at the bottom end substantially within the diameter of the cylindrical vial body. Peripheral beads around the openings of glass bodies of this type are conventionally formed by flame softening the glass and adjusting the positioning and profile of the bead by rolling the body against suitable forming surfaces. In the FIG. 5 embodiment, a bottom portion 274 of the body 204 is flame softened and rolled so as slightly to reduce its diameter over about a length of typically 5-6 mm, and a fairly conventional out-turned rounded bead 206 is formed by flaring the bottom of this reduced diameter section. The reduction in diameter is such that at least the greater part of the bead is within the general diameter of the body. In the example shown, the outside diameter of the bead is very slightly greater than the general outside diameter of the body but this need not be so. In a typical example, the inside and outside diameters of the main portion of the vial body are 27 mm and 30 mm respectively, providing a wall thickness of 1.5 mm, and the reduction in diameter at the bottom is about 1 mm. The bead can then be formed by flaring the bottom end of the vial without increasing the outside diameter of the bead significantly beyond that of the main portion of the vial and typically by no more than 0.5 mm, even though a significant flare 276 can be provided and, because of the flare, the bottom contact line 278 of the vial when free-standing on a plane surface is substantially coincident with the outside diameter of the main body 204 of the vial, thus maximizing stability. Juxtaposition of the vial bodies in the event of jostling on a line will prevent any ramping tendencies which might otherwise occur with a flared bottom configuration of this type.

Whilst the presence of the piston after its insertion in the vial body acts to introduce a substantial mass which tends to stabilize the vial, the mass of the piston relative to that of the vial body will decrease as the height of the latter increases. Nevertheless it will result in a smaller rise of the centre of gravity of the assembly as the vial becomes higher than would otherwise be the case. It is also desirable that the vial bodies be stable without the piston present so that they may be conveyed through a stabilizer prior to insertion of the pistons. The present invention is particularly valuable in this respect since the disturbing influence of a bead at the open end projecting beyond the diameter of the main portion of the body is particularly severe under such conditions.

In order to cooperate with the modified vial body profile, the finger grip/retainer 216 must also be modified. The groove 270 is replaced by a bead 280 at the upper end of the cylindrical portion 218, which bead may be moulded with a taper and if necessary with slots 282 to facilitate insertion, and/or the component 16 may be warmed to facilitate insertion. The bead must retain the component with sufficient tenacity to withstand pressures from the piston which may be developed through pressure build-up in the vial during normal storage, although it should be noted that pressure of the piston on the bead may actually help retain it by forcing it against the shoulder 284. Alternatively or additionally, claws 286 may be moulded onto the component 216 to retain it by external engagement with the bead 206.

A further development of the embodiment of FIG. 11 is shown in FIGS. 12 and 13. A body 402 for a bottomless vial is moulded from glass or synthetic plastic material, with a generally cylindrical form having shoulders 404, at the top end connecting to a hollow neck 406. At a bottom end of the body its side wall is formed with a rounded or beaded bottom edge 408 to form an open bottom end through which a piston 410 may be inserted.

A portion 416 of the inside side wall adjacent the bottom edge 408 is tapered inwardly and joined to the remainder of the side wall by a peripheral jog 412 so as to provide a narrow internal upwardly facing annular shelf or shoulder 414 above a funnel-shaped upwardly tapered bottom entry to the interior of the body. The shelf and tapered bottom entry may be formed by rolling a heat softened bottom portion of the wall against a suitably shaped mandrel, in which case the outer face of the wall will be recessed as shown at 418, or may be moulded in which case the outer recess may not be

present. In either case, there will be no projection, or at least no significant projection, of the outer face of the moulded or rolled portion of the wall outside the circumference of the remainder of the wall. The tapered bottom entry assists in insertion of the piston 410, and subsequent insertion of the retainer ring 420 described below.

The retainer ring 420 is moulded from synthetic plastic material and provided with a radially extending flange 422, and has a tapered upper portion 424 having a maximum diameter approximately equal to the internal diameter of the body 402 above the shelf 414, but greater than the internal diameter of the shelf, and a minimum diameter such that it can readily start to enter the tapered bottom entry to the body. A lower portion 426 of the ring above the flange 422 has a smaller external diameter and a height at least equal to the height of portion 416 so that the ring may be pressed into the tapered entry until a shoulder 428 between the upper and lower portions snaps over the shelf 414, thus positively retaining the ring. Preferably the lower portion 426 has an internal profile and height such as to provide snug accommodation of the portion 416 with due allowance for manufacturing tolerances. A small recess 430 may be formed in the inside wall of the body adjacent the shelf 414 to provide additional clearance for the shoulder 428.

The flange 422 is of limited radial extent so that it does not extend beyond the external diameter of the vial body, so that the retainer ring 420 may be inserted prior to filling and capping, but in this case it cannot also provide a finger flange. This problem can be overcome if a flange is required by providing a separately moulded flange 432, with an annular forwardly projecting locking ring 434 which can be snapped into annular groove 436 formed within the ring 420 prior to use of the vial.

I claim:

1. A pharmaceutical vial used for forming a barrel and a piston of a syringe after being filled and capped, comprising a cylindrical glass vial body having at one end an integral open neck and a peripheral external flange around an outer end of the neck, a peripheral rounded edge defining an inner periphery of an open opposite end, and a piston of resilient material having a cylindrical head within and concentric with the cylindrical glass body, the piston maintaining a slidable hermetically sealing relationship with a main inner cylindrical surface of the body, and being located to define a chamber of volume equal to the nominal capacity of the vial between the piston head and the neck of the vial, the piston having integral coupling structure wholly within the body for subsequent connection to a syringe plunger, and the vial being stable when standing on the open end of the body such that it can be conveyed while so standing through vial filling and capping machinery without tipping over, the body being formed adjacent said open end with peripheral radially exteoding positive retention means for engagement with complementary configurations of a tubular piston retaining member subsequently inserted within said open end of the body to resist overpressure within the body, wherein the retention means is formed by shaping a lower end portion of the body to have a reduced internal diameter such that the retention means is formed by an upwardly facing shoulder at the top of the lower end portion which projects inwardly of the projected circumference of said main interior cylindrical surface, and the lower end portion is located essentially within the projected circumference of a main cylindrical external surface of the body such as to leave the external surface of the body free of projections having an adverse effect on the stability of the vial;

said vial further including a pharmaceutically project within the chamber, a needle penetrable stopper inserted in the neck, and an annular cap crimped over said stopper and the flange of the neck to retain the stopper in hermetic engagement with the neck, the cap being provided with a concentric tubular outward extension for receiving one of a double ended hollow needle and an adaptor for receiving a single ended hollow needle such that one end of the double ended needle, or a hollow needle provided on the adaptor, can penetrate the stopper, and including a finger grip and piston retainer member, wherein the piston retainer member includes a tubular member which is a press fit within the open end of the body of the vial, and a flange at an outer end of the tubular member providing outwardly extending finger tabs, the tubular member being recessed in its external surface adjacent the flange in the vicinity of the finger tabs so as to receive the retention means inward of the interior wall of the body.

2. A vial according to claim 1, wherein a generally cylindrical bottom portion of the body is of reduced internal and external diameter such as to provide a peripheral shoulder between said main internal cylindrical surface and an internal cylindrical surface of said bottom portion, and an outer cylindrical surface of said bottom portion has an external periphery which is essentially within the projected circumference of a main cylindrical external surface of the body, said shoulder forming said retention means, and the reduced internal diameter of the bottom portion being insufficient to prevent insertion of the piston therethrough.

3. A bottomless pharmaceutical vial for incorporation into a syringe, comprising a generally upright cylindrical hollow body with a narrower neck at its top end, a side wall of the body being formed with a bottom edge surrounding a flared bottom opening, with an inner surface of a lower portion of the side wall of the body adjacent said bottom opening extending upwardly to an outward jog in said inner surface, the jog forming an upwardly facing annular shoulder, and the lower portion of the side wall being substantially wholly within a downward projection of an outer surface of the remainder of the side wall, a piston within the body, and a piston retainer ring inserted into the bottom opening of the body beneath the piston, the piston retainer ring having an outer surface with an upper portion tapered to enter the flare of the inner wall of the body adjacent said bottom opening, a lower portion of reduced external diameter, and a downwardly facing shoulder connecting said upper and lower outer face portions, such that the ring may be pressed into said bottom opening until the shoulder snaps over the shelf to retain the ring.

4. A vial according to claim 3, wherein the retainer ring is wholly inward of the downward projection of the outer surface of the side wall.

5. A vial according to claim 4, wherein the retainer ring includes a flange extending beneath the bottom edge of the body but having a diameter no greater than that of the body.

6. A vial according to claim 5, wherein the flange has an internal peripheral groove, and including a separately formed finger flange with a locking ring for subsequent engagement with the groove.

7. A vial according to claim 4, including a separately formed finger flange for connection to the retainer ring following filling and capping of the vial.

8. Syringe kit, comprising:

(i) a first subassembly comprising:

(a) a glass pharmaceutical vial having an external configuration which is that of a glass serum vial and handleable by filling and caping machinery designed

for filling and capping serum vials, but with a circular bottom opening in a horizontal plane defined by a bottom edge if a cylindrical side wall of the vial, any external projection at said bottom edge of the said wall being insufficient to prejudice the stability of the vial when conveyed free-standing through such filling and capping machinery;

(b) a piston including means for subsequent coupling of said piston to a plunger, the piston being formed of resilient material and having sufficient solidity in the absence of the plunger to ensure an hermetic seal with said vial side wall, the piston, including said coupling means, being received wholly within said vial;

(c) a pharmaceutical filled within said vial above said piston through an open neck thereof by a vial filling machine; and

(d) a closure applied to the open neck at the top of the vial and retained thereon by an annular cap, the cap and closure being applied by vial capping machinery;

(ii) means applicable to said annular cap and axially displaceable on use of the syringe to project a cannula through said closure into said vial and thus place said vial in communication with means for injecting its contents;

(iii) a plunger engageable with said coupling means to enable the piston to be projected towards said neck within said side wall to expel said pharmaceutical through said injection means; and

wherein a shoulder is formed within said bottom edge of the cylindrical side wall, and further including a piston retainer ring engageable with the shoulder within the vial.

9. A kit according to claim 8, further including means for providing a finger grip on said first subassembly and engaging said vial to facilitate operation of said plunger.

10. A kit according to claim 8, wherein the axially displaceable means applicable to the annular cap and the plunger form parts of a second subassembly including said annular cap and the plunger.

11. In a method of producing a prefilled syringe for administering a pharmaceutical preparation, said syringe comprising a generally cylindrical syringe body having a neck at one end and a side wall having a bead finish at the other end, at least a component of the preparation filled into said body, an elastomeric closure closing the body at the neck end and secured by a cap, and an elastomeric piston at said other end forming a hermetic seal with an inside surface of said side wall, needle means for movement relative to the cap to penetrate the elastomeric closure, and plunger means for connection to an outer side of the piston, the improvement wherein:

the syringe is produced by associating components, including said plunger and said needle, with a prefilled vial produced by:

forming said body with height to diameter ratio such that the body is stable, and so that any outward extent of the bead is insufficient to result in interference such as would cause tipping, when the body is conveyed standing on said other end through equipment for filling and capping pharmaceutical vials;

inserting said elastomeric piston wholly within said other end of the body to form a vial open at the neck; and

filling said vial through said neck with said pharmaceutical preparation component, and then applying said elastomeric closure to said cap, whilst conveying the vial standing on said other end through equipment for filling and capping pharmaceutical vials.

12. A method according to claim 11, wherein the association of other components includes engaging a piston retainer within said other end of the vial after filling and capping, and wherein the vial with the piston retainer applied is heat sterilized.

13. A method according to claim 11, wherein the step of forming said body so that any outward extent of the bead is insufficient to result in interference such as would cause tipping includes forming the bead to provide an upwardly facing shoulder projecting inwardly of the wall of the body.

14. A method according to claim 11, wherein the step of forming said body so that any outward extent of the bead is insufficient to result in interference such as would cause tipping includes slightly reducing the diameter of a bottom portion of the body, and flaring the open end of said reduced diameter portion of the body to form said bead.

* * * * *

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United States Patent [19]

Reynolds

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[45] Date of Patent: Aug. 11, 1992

[54] SYRINGE

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[73] Assignee: Duoject Medical Systems Inc., Lac Brome, Canada

[21] Appl. No.: 437,203

[22] Filed: Nov. 16, 1989

Related U.S. Application Data

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[51] Int. Cl.[5] A61M 5/00

[52] U.S. Cl. 604/88; 604/416; 604/413; 604/191

[58] Field of Search 604/82, 87, 88, 89, 604/91, 92, 191, 200, 201, 413, 414, 416

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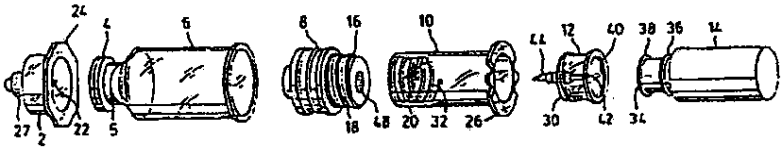
Primary Examiner—Stephen C. Pellegrino

Assistant Examiner—Ralph A. Lewis

[57] ABSTRACT

A prefilled syringe for one or two component medicaments is based upon the use of a vial containing a medicament or one component of a medicament, the vial having an open bottom closed by a piston. When a flexible extension of the piston is coupled with a tubular plunger, and an adaptor cap having an internal needle and an external connection for a needle is placed over a cap of the vial, the latter is converted into a prefilled syringe. The piston may have an axial passage closed by a resealable septum, so that a separate diluent stored in a flexible capsule may be introduced into the vial through the piston by a double ended needle mounted on a further cap applied to the capsule, the further cap being coupled within the tubular interior of the plunger so that the double ended needle penetrates the septum in the piston. The capsule is pushed forward onto the double ended needle when its contents are to be expelled into the vial. The capsule and its cap are then removed and discarded. In an alternative arrangement, the cap of the capsule is coupled to the adaptor cap and the diluent introduced into the vial through a closure secured by the cap of the vial, after which the capsule is removed from the plunger and the latter is coupled to the piston.

11 Claims, 8 Drawing Sheets



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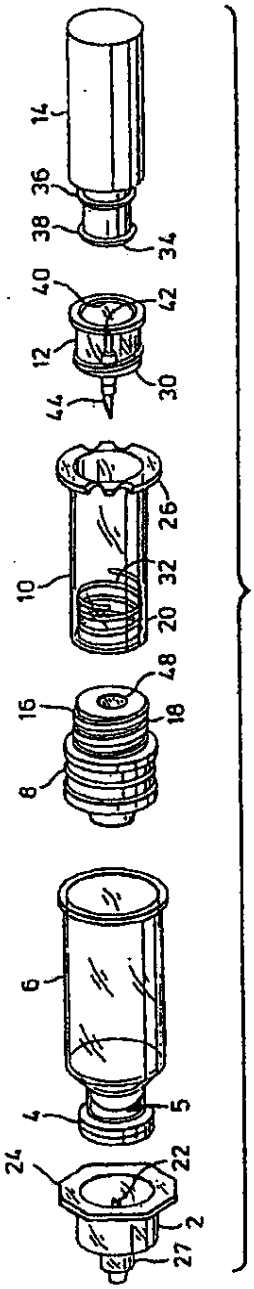
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FIG. 1

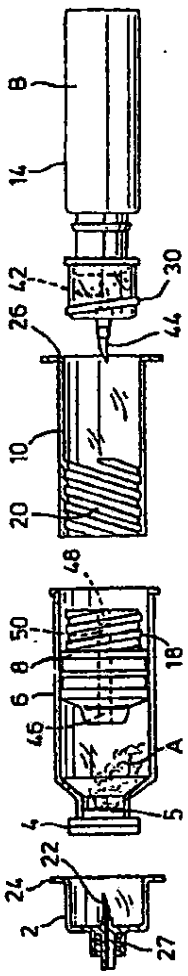
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FIG. 2

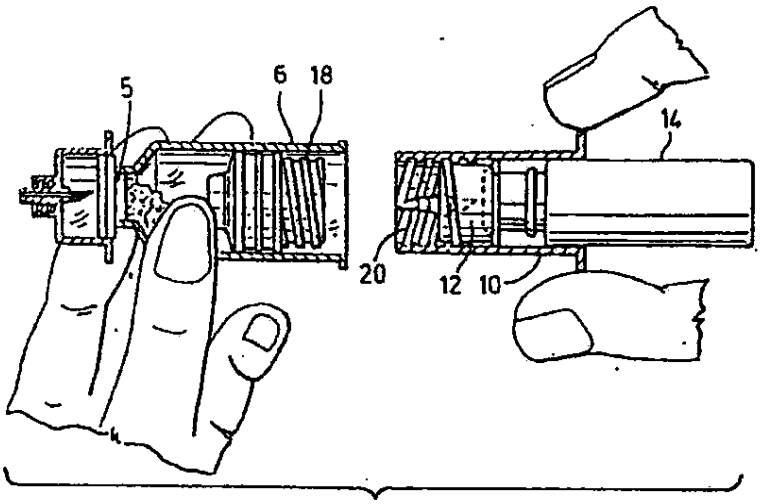


FIG. 3

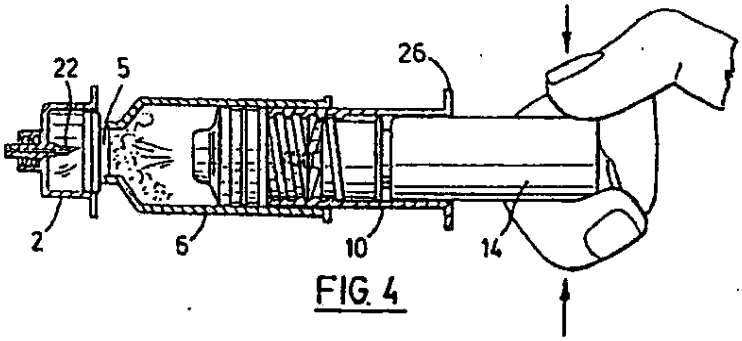


FIG. 4

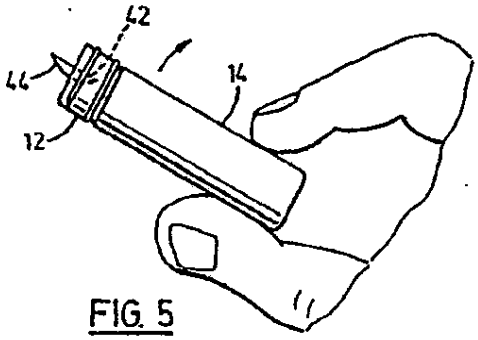


FIG. 5

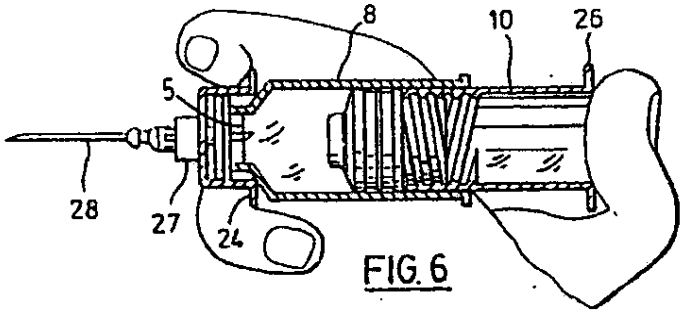


FIG. 6

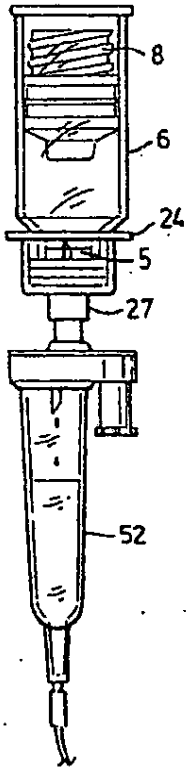


FIG. 7

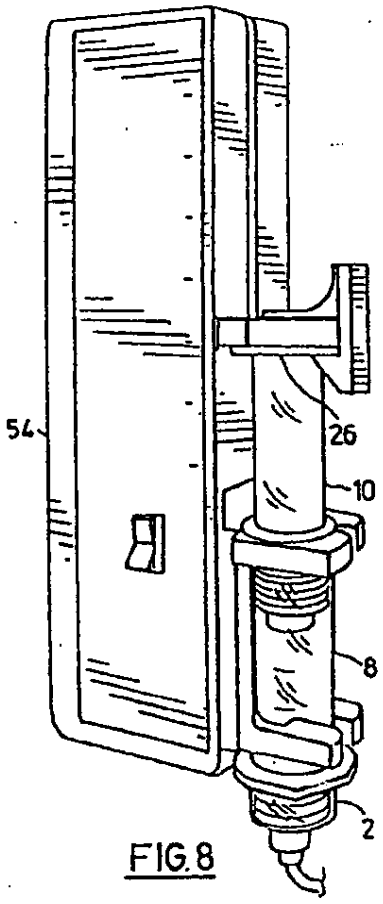
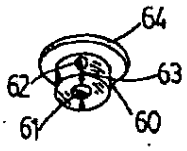


FIG. 8

FIG. 9



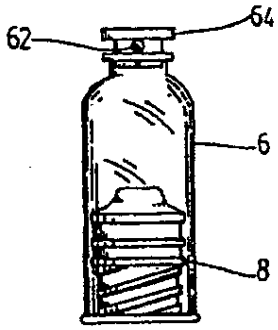


FIG. 10

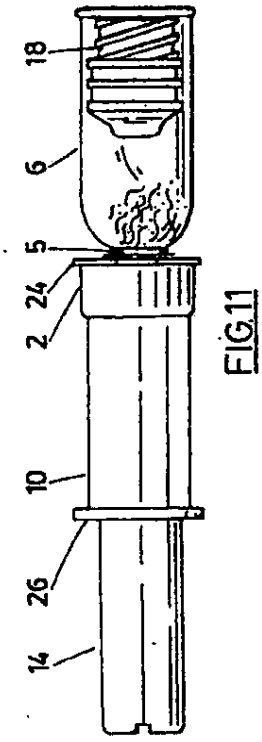


FIG11

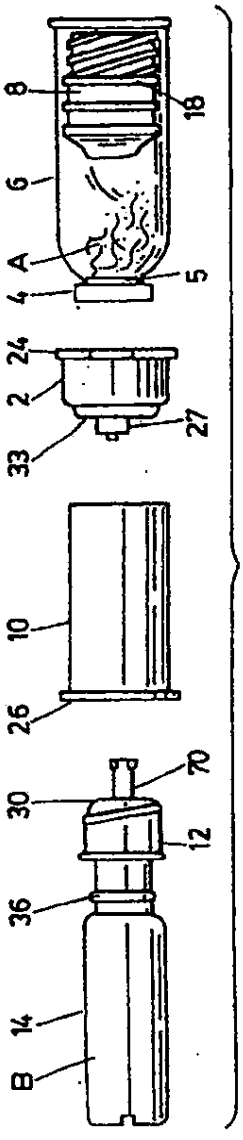


FIG12

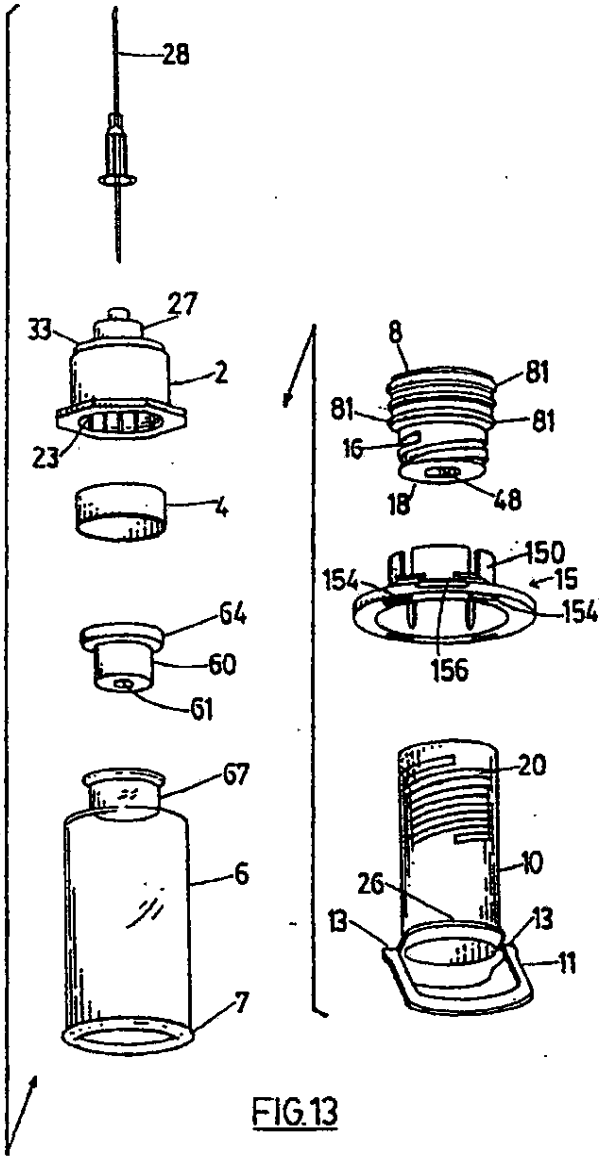

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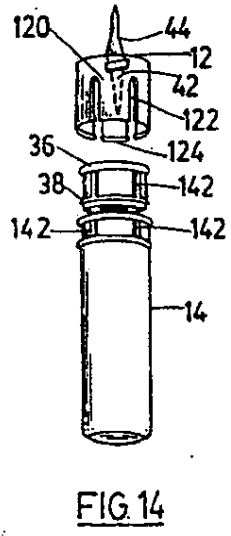
FIG.13


120
44
12
42
122
36
124
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142
142
142
14

FIG. 14

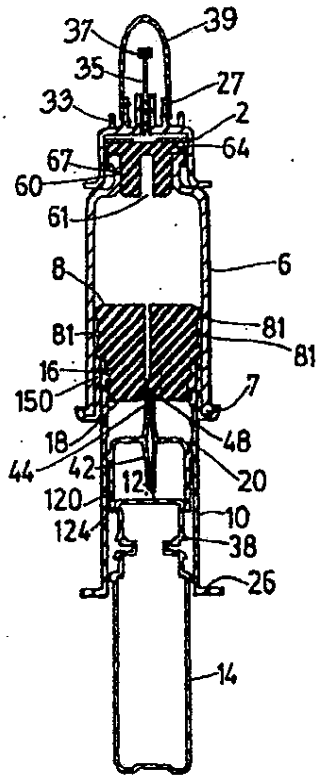
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FIG. 15

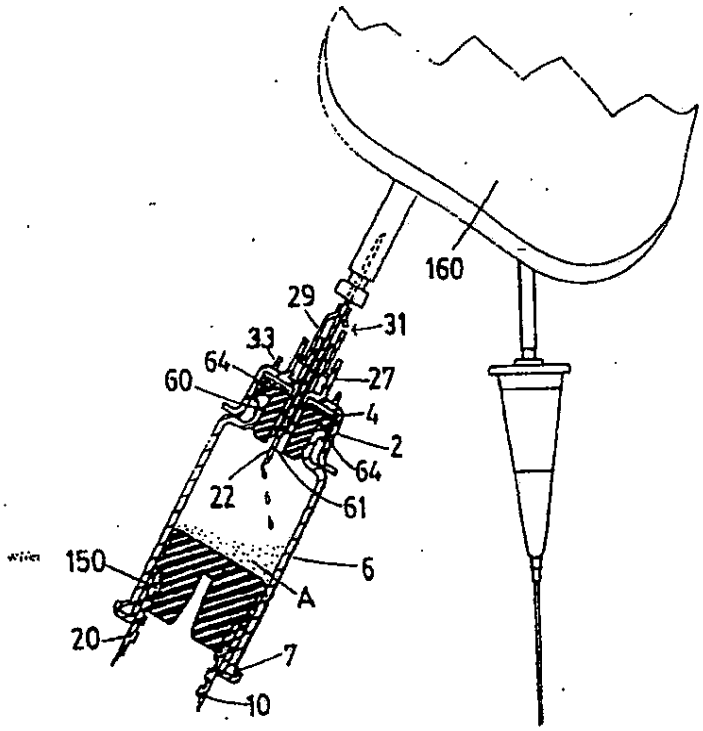

FIG.16

SYRINGE

BACKGROUND OF THE INVENTION

This application is a continuation in part of Ser. No. 072,015 filed Jul. 8, 1987 now U.S. Pat. No. 4,886,495.

FIELD OF THE INVENTION

This invention relates to prefilled syringes for use in medical or veterinary treatment.

REVIEW OF THE ART

There has been an increasing trend in recent years to the putting up of pharmaceuticals in dosage forms so as to minimize the preparation required to administer a medicament to a patient and to reduce the chances of dosage errors or contamination. One dosage form which has been gaining rapid acceptance is the prefilled disposable syringe. Various difficulties are however associated with the preparation and usage of such syringes, particularly in the case of preparations which, in ready to use condition, have a short shelf life. Numerous forms of dual compartment syringe structures have been proposed for the shipping of such preparations with components stored in separate compartments for admixture immediately prior to use. Although certain structures have met with some degree of acceptance, they are commonly difficult to manufacture and/or use because of difficulties in filling the syringe with the components, and because they require extensive manipulation immediately prior to use. Moreover they are frequently substantially more bulky than conventional syringes because in many cases they frequently comprise components which effectively represent two syringes in tandem.

Problems in the manufacture of prefilled syringes are not confined to two component systems and even with single component systems the filling of syringes under factory conditions is difficult to mechanize effectively and requires expensive special purpose syringe filling machinery. The same applies to related units prefilled with liquids required for injection or infusion during medical procedures.

Another approach where single component systems are involved is exemplified by British Patent Specifications Nos. 1,252,306 and 1,444,119, and U.S. Pat. No. 4,445,895, in which a prefilled cartridge having a displaceable plug at one end, and a needle penetrable closure at an opposite end, is inserted into the barrel of a syringe for dispensing of its contents. Whilst such cartridges and the equipment for filling them are known and available, they are only really suitable for preparations which can be stored in liquid form, and require either a special or a modified syringe for their use. The cartridges themselves require special filling apparatus.

In a further arrangement disclosed in U.S. Pat. No. 3,845,763, a cartridge or vial is closed at its bottom end by a slidable plug with a downwardly extending stem, which cartridge or vial is inserted bottom end first into a special holder which carries a double ended needle, so that the stem is penetrated by the needle and the body of the vial is converted into a plunger which can be depressed to expel the contents of the vial through the stem. The projecting stem means that the vial cannot be filled utilizing conventional vial filling machinery.

The high capital expenditure involved in implementing known prefilled syringe systems has severely limited their adoption to those few cases where their advantages outweigh the substantial additional unit costs involved as compared to conventional modes of delivery.

SUMMARY OF THE INVENTION

The present invention seeks to provide a system for the distribution of preparations required for injection or infusion in liquid dosage form during medical procedures, which has a wide range of utility both for single component liquid preparations or for two component systems of which one component may be a solid, which utilizes a small number of components all suitable for mass production using material already approved for usage in such applications, and which is simple to assemble and can be filled utilizing equipment already available to most pharmaceutical manufacturers.

The system is based upon and built around a basic component in the form of a "bottomless vial". Such a bottomless vial has all of the characteristics of a conventional pharmaceutical vial, except that the glass base of the vial is replaced by a piston wholly received within the vial and designed to form a hermetic seal with its cylindrical side wall, the seal being maintained both when coupled and when uncoupled from a plunger releasably connectable to the piston for moving the latter axially of the vial. A particularly important characteristic of such a bottomless vial is that it can be conveyed, filled and capped reliably by conventional vial filling and handling equipment such as is already possessed by most pharmaceutical manufacturers. To this end, the bottomless vial must be free of features which would significantly compromise its stability when handled by such equipment. Thus any flange around the base of the vial must result in no more than a slight increase in the overall diameter of the vial, so as to avoid any substantial increase in its tendency to tip when jostled by other similar vials, and the center of gravity of the vial must not be displaced so far upwardly as to substantially reduce the stability of the vial.

The piston must be capable of maintaining a hermetic seal with the wall of the vial of integrity comparable to that achieved during capping of a conventional vial, and this seal should be maintained during manipulation of a syringe system incorporating the vial, during which the piston may be subject to non-axial forces transmitted to it by a plunger and tending to break the seal.

In the context of the invention, it should be understood that "vial" refers to a particular type of container, having a rather squat cylindrical body whose height compared to the diameter of its base is such that it may stand stably on its base whilst being conveyed through a vial filling machine and subsequently sealed and capped. Its body should also be free of external projections large enough to interact with other vials or the filling machinery in a manner such as to promote tipping. A vial has a neck with a large enough internal diameter to permit filling from a vial filling machine: solid filling materials will normally require a larger neck than liquids. Vials should not be confused with cartridges, which are comparatively long and slim, and cannot usually be filled utilizing vial filling machinery since they are too tall to rest in a stable manner on their bases.

Accordingly the present invention provides a vial formed of rigid transparent material and consisting of a cylindrical body, said body having an open bottom end

having an external diameter at most only slightly greater than that of the remainder of the body, but sufficient relative to the height and center of gravity of the vial as a whole to support the latter in a stable manner when conveyed standing on its open end through vial filling and capping machinery, injectable material within the body, a comparatively wide neck at the top of the body through which said injectable material is filled into the body, an external peripheral flange surrounding the neck, an elastomeric closure applied to the neck, a cylindrical cap clamped onto the flange of the neck and having an annular inward extending flange at a top end overlaying the closure to secure the closure to the neck with the closure presenting a needle penetrable central portion, an impervious substantially solid piston of resilient material sealingly received within said body at its lower end beneath said injectable material and above said open bottom end, and an extension integral with said piston, projecting downwardly from said piston but wholly within the body, for establishing a flexible connection to a syringe plunger in a zone between the piston and said open end of the body, whereby said vial may be converted into a syringe for ejection of the injectable material on movement of the piston towards the neck, by connection of said syringe plunger to said extension and connection of fluid conduit coupling means to said cylindrical cap.

The differences between such a vial and a conventional vial do not prevent it from being filled and capped in conventional vial filling and capping machinery; indeed, apart from the replacement of the bottom wall of the vial by a piston as specified, it is a conventional vial, and can be handled normally by the machinery during filling with either liquid or solid material. The presence of the piston which is relatively massive, in the lower part of the vial even helps stabilize the latter during filling. Furthermore, liquid filled vials may be lyophilized utilizing special stoppers either as known in the art or as described below. Obviously the cubic capacity of such a vial is less than the capacity of a conventional vial of comparable overall dimensions but for most purposes this is immaterial.

A vial in accordance with the invention may be converted into a syringe by the addition of a plunger coupled to the piston and an outer cap which acts as a needle carrier. More specifically, the syringe includes as well as the vial a syringe plunger connected to the flexible extension from the piston, and an outer cap engaged over the cap of the vial, the outer cap having a hollow needle projecting axially within the cap and a coupling for engagement with injection means and communicating with said hollow needle, the outer cap being axially movable relative to said cap of the vial from a position in which the needle ends short of the cap of the vial to a position in which it penetrates the cap of the vial. The plunger is provided with radially extending flanges for sustaining actuating forces applied to the syringe through a flange grip provided on the outer cap or on a plunger guide or piston stabilizer ring applied to the open end of the vial.

In a syringe for a two component medicament, it is necessary to provide for packaging of the second component and its admixture with the first component in the vial prior to dispensing. The invention thus further extends to a capsule assembly comprising a generally cylindrical sealed capsule having walls formed of a flexible needle penetrable material of suitable properties, a generally cylindrical neck defined by said walls at one end of the capsule, said neck having axially spaced inner and outer peripheral ridges, and a generally cylindrical cap applied to said neck so that a detent within the cap engages the outer peripheral ridge on the neck, a hollow cannula being formed integral with and passing through said cap so that an inner penetrating end within the cap ends short of the neck of the capsule and an outer end formed either in the form of a needle or a fluid coupling which extends outwardly of the cap, the cap being displaceable relative to the capsule to a position in which the detent rides over the inner ridge and the inner end of the needle penetrates the neck of the capsule, the cap and capsule being of a diameter such that they can enter the tubular plunger to a position in which the outer end of the cannula, if of needle form penetrates the septum of the piston when the plunger is engaged with the latter. An alternative arrangement may be used where the outer end of the cannula is a coupling, in which case the latter is connected to the coupling on the outer cap of the syringe, with the plunger being used as a support for the capsule prior to being coupled to the piston.

Thus the injection system comprises a sequence of components of which various sub-sequences can be combined to form injection systems for preparations requiring shipping and storage as two separate components, certain sub-sequences themselves having utility respectively as injection systems for single component liquid preparations. "Injection" is utilized broadly to cover hypodermic, intramuscular and intravenous injection, gravity and mechanical infusion, and injection into other vessels utilized in medical treatment or testing. For the purposes of description, the "front" or "top" end of an injection system will be considered the end of the system from which a liquid preparation is so injected.

The arrangement including the capsule assembly has a number of advantages in the manufacture and use of prefilled syringes for two component systems; furthermore, without the third cap and the sealed capsule containing the second component the remaining components provide, according to a further feature of the invention, advantages in the manufacture and use of prefilled syringes for single component systems. The third cap and sealed capsule provide, according to yet a further feature of the invention, an advantageous subsystem for various applications in which a sealed sterile source of a liquid is required for injection, or dropwise introduction into other containers used in medical procedures. With prefilled syringes for two components systems, either the capsule or the capsule and the third cap, may be sold, or shipped separately. This enables different diluents or sizes of capsule to be selected, or a common set of diluent capsules to be utilized with syringe assemblies containing different first components, thus simplifying inventory control.

Further features of the invention will become apparent from the following description of a preferred embodiment thereof with reference to the accompanying drawings.

SHORT DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective exploded view of the mechanical components of a syringe system including a vial in accordance with the invention;

FIG. 2 is a partially longitudinally sectioned, partially exploded view of the syringe components showing some further details of their construction;

FIGS. 3, 4 and 5 illustrate preparation of the syringe system to provide a syringe ready for use;

FIGS. 6, 7 and 8 illustrate exemplary applications of the syringe;

FIGS. 9 and 10 illustrate an optional feature of a vial in accordance with the invention;

FIGS. 11 and 12 are elevational and exploded views of an alternative embodiment of the syringe system;

FIG. 13 shows the separated parts a further embodiment of the syringe system;

FIG. 14 shows, separated, a diluent capsule and cap for use with the system of FIG. 13;

FIG. 15 is a longitudinal cross section through the assembled system of FIGS. 13 and 14; and

FIG. 16 is a fragmentary view of a syringe in accordance with the invention utilized in conjunction with an I.V. bag.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIGS. 1 and 2, a syringe system for the injection of a liquid preparation stored as two components comprises seven primary mechanical components, apart from the components of the preparation, which latter are shown in FIG. 2 but not FIG. 1. The components of the preparation typically comprise a first component A which may be in any physical state suitable for storage in vial, and a second liquid component B, typically but not necessarily sterile water. The liquid component B is stored in a sealed capsule 14 of flexible material, manufactured using conventional techniques from a material, usually synthetic plastic, which is compatible with the contents of the capsule. The first component is stored in a cylindrical vial 6, typically of glass, and capped by an annular cap 4 which retains a conventional needle penetrable sealing member accessible through a central opening in the cap. By a vial is meant a cylindrical vessel which can assume a stable upright position supported by its base, the overall height of the vessel preferably not exceeding 2.5 times the external diameter of the rim of its base so that it remains stable when passing through conventional vial filling and capping equipment utilized to fill and cap the vial. A neck at the upper end of the vial 6, which is capped by the cap 4, has a relatively internal diameter characteristic of such vessels, usually not less than about 7.5 mm for liquid or 10 mm for solids, so that filling either liquids or solids can be readily achieved. The cap 4 is formed by an aluminum sleeve, having a flange retaining a sealing member formed by a soft rubber disc or plug 5 over or in the front end opening, and tightly crimped onto a neck at the front end of the vial so as to seal the latter. A major difference from conventional vials is that the conventional bottom wall of the vial is replaced by an axially movable piston 8 wholly within the vial and in sealing contact with the vial walls. When received within the vial 6, this piston in no way interferes with the handling of the vial using conventional machinery, and in particular permits the vial to be stood on its base with its neck (which forms the front end of the vial when in use) upwards as it passes through the filling and capping equipment.

The filled vial 6 may be converted into a prefilled syringe by applying an outer cap 2 over the cap 4 and positively attaching a cylindrical plunger sleeve 10 to the piston 8. The piston 8, typically formed of rubber, is moulded with a rearward extension 16 with an external thread 18, whilst the interior of the front end of the plunger sleeve 10 is formed with a complementary internal thread 20 so that it may be screwed onto the piston 8. The outer cap 2 fits over the inner cap 4 so that a hollow needle 22 formed within the cap 2 does not reach the penetrable zone of the cap 4. On the front of the cap 2 and in communication with the hollow needle 2 is a coupling adapter 27, for example similar to those sold under the trade mark LUER-LOK, for connection of the syringe to a needle 28 or other instrumentality (see FIGS. 6–8). To prepare the syringe for use, the outer cap 2 is pulled back over the inner cap 4 so that the needle 22 penetrates the cap, and the needle 28 or other instrumentality is applied. This should be done without pressing on the plunger sleeve so as to avoid accidental ejection of the contents of the syringe. The rear ends of both cap 2 and the sleeve 10 are formed with radially extending flanges 24 and 26 respectively which form finger grips for operation of the syringe. Thus if a user grips the syringe by the flanges as shown in FIG. 6 and presses them towards each other, the contents of the syringe can be expelled through the needle 22 and the needle 28. It will be noted that the rear end of the vial 6 is formed with only a relatively slight external bead 7 rather than the wide finger flange commonly found on the barrels of conventional syringes. In the present arrangement, the flange 24 provides the function of such a finger flange, enabling the bead 7 to be reduced to a size which will avoid such interference between the flanges of adjacent vials as would cause tipping when the vials are conveyed in a vertical attitude through filling and capping equipment.

In many applications, it is desirable to prevent premature penetration of the plug 5 by the needle 22, and therefore the cap 2 may be moulded with short internal threads (not shown) which prevent rearward movement of the cap 2 unless it is twisted so that the threads bite into the soft aluminum of the cap 4 and draw the cap 2 rearwardly so that the needle 22 can penetrate the plug.

A prefilled syringe constructed as discussed above has significant advantages over conventional prefilled syringes in that the vial may be filled using conventional vial filling equipment, and yet may be utilized directly instead of requiring its contents to be transferred to a syringe prior to use as has been conventional in the use of vials.

The vial may also be charged with material which is not directly injectable, such as solids which must be dissolved or suspended in a liquid medium prior to injection. In this case the liquid medium is sealed as already described in a flexible capsule 14. A third cap 12 is either applied to the capsule as shown in FIG. 2, or inserted into the plunger sleeve 10 so that a screw thread 30 on the exterior of the cap engages the screw thread 20 within the sleeve.

A neck 34 of the capsule 14 has two peripheral ridges 36 and 38. If the cap 12 is applied to the capsule, a detent 40 within the cap is pushed over only the outer ridge 38 so that a rear end portion 42 of a hollow needle mounted in the cap stops short of the end of the capsule. By forcing the detent 40 rearwardly over the ridge 36, the needle portion 42 can be forced rearwardly so as to penetrate the capsule. A forward end portion 44 of the hollow needle has a length such that when the cap 12 is screwed into the sleeve 10, and the sleeve 10 is screwed onto the piston 8, the needle portion 44 penetrates a resilient septum 50 normally separating axial passages 46 and 48 formed in the front and rear of the piston.

In use, if the capsule 14 and cap 12 are shipped as a separate unit, this unit is screwed into the sleeve 10 (see FIG. 3), and the sleeve 10 is pushed into the rear of the vial 6 so that the needle portion 44 penetrates the septum 50 of the piston 8 and the thread 20 is screwed onto the thread 18 of the piston (see FIG. 4). This action also substantially unscrews the cap 12 from the thread 20. The capsule 14 is then pressed forward onto the needle portion 42, and the liquid contents of the capsule can then be squeezed through the needle and into admixture with the first component in front of the piston 8. Thereafter the capsule 14 and cap 12 may be pulled as a unit from the sleeve 10 and discarded (see FIG. 5). The septum 50 reseals as the needle portion 44 is withdrawn, leaving a syringe ready for use as illustrated in FIGS. 6-8. Alternatively, if the cap 12 is prefitted to the sleeve, the sleeve 10 may be screwed onto the piston 8, and the capsule 14 pressed into the sleeve 10 and the cap 12 so as to establish communication between the capsule and the space forward of the piston, the procedure thereafter being the same.

Rather than being used conventionally with a needle as shown in FIG. 6, the prepared syringe may be used for gravitational or mechanical infusion as shown in FIGS. 7 and 8. In FIG. 7, the adapter 27 is fitted to a complementary coupling on a gravity infuser 52 to provide a drip feed, the sleeve 10 having been unscrewed and discarded, together with the cap 12 and capsule 14, if used. In FIG. 8, the syringe is mounted in a mechanical infuser 54 such as that sold under the trade mark BARD, the latter being equipped with clamps 56, 58, 60 suited for engagement with the syringe.

By basing the system on an open-bottomed vial 6 closed at its bottom end by a piston 8 equipped with means such as the screw-thread 18 for coupling it to a plunger of sleeve form, and with a needle penetrable septum 50, in optional conjunction with sealed flexible capsules of diluent, great flexibility in application can be obtained, using components which are easy to fill, compact to ship, and easy to make ready for use.

Referring now to FIGS. 9 and 10, the rubber disk or plug retained by the cap 4 on the vial 6 may be replaced by a modified plug 60 as shown in perspective from beneath and one side in FIG. 8, and partially installed on a vial 6 in FIG. 9. Use of such a plug 60 is advantageous when the solid component of a medicament is to be prepared in situ in the vial by lyophilization. The vial is filled with a liquid preparation to be lyophilized, and plug 60 inserted to the position shown in FIG. 9, so that the interior of the vial communicates with its environment through a central passageway 61 and radial bores 62, the passageway and the bores being no larger than needed for the removal of water vapour during lyophilization. The plug is split at 63 to facilitate moulding. After filling the contents of the vial are rapidly frozen and vacuum dried to leave a solid residue in the vial which can be reconstituted immediately before use. The plug 60 is then moved to the full extent permitted by a flange 64 into the neck of the vial 6 and secured by a cap 4. Whilst a conventional lyophilization stopper could be utilized in place of the plug 60, the latter has the advantage of minimizing the amount of liquid trapped within the stopper during use of the syringe. For the same reason, the head of the piston 8 is shaped so as to minimize dead space in the neck of the vial when the contents of the vial are expelled during use of the syringe.

FIGS. 11 and 12 illustrate an alternate configuration of the syringe. The various components are essentially identical to those already described, and the same reference numerals are utilized except that the outer needle 44 of the conduit extending through the cap 12 is replaced by an extension 70 which is configured at its outer end to couple with a standard syringe coupling such as the coupling 27 on the cap 2. This enables the capsule 14, once inserted in the plunger 10, to be locked through the extension 70 and the coupling 27 to the cap 2 to produce the compact assembly shown in FIG. 11. The inner end of the plunger 10 is a press fit on an annular retaining flange 33 formed on the cap 2. To prepare the syringe for use, the cap 2 is forced rearwardly over the cap 4 so that the needle 22 (see FIG. 2) pierces the seal 5, and the capsule 14 is forced forward so that it is pierced by the needle 42 and its contents can be expelled through the needle 42, the extension 70, the coupling 27 and the needle 22 into the vial 6. The assembly of the capsule 14 and the plunger 10 can then be released from the remainder of the syringe by turning so as to release the extension 70 from the coupling 27, a needle (not shown) may be applied to the coupling 27, the capsule 14 is removed from the plunger 11 and discarded, and the plunger 11 is screwed onto the coupling 18 to ready the syringe for use. With this arrangement, the passage 46 in the piston 8 is not required, although the passage 48 may be retained to save material and enhance the flexibility of the extension 18 of the piston.

A similar arrangement may be utilized for single component medicaments in which case the capsule 14 and cap 12 are not provided. The arrangement is advantageous for both single and multiple component medicaments since only the vial need be assembled and filled in a clean room, the only additional step required over the filling of a conventional vial being the insertion of the piston 8. The plunger 10 may be pressed onto the cap 2, and this assembly, if desired together with a needle and/or a capsule 12 and cap 14, may be separately sterilized and packaged, without endangering the stability or destroying the contents of the vial, which will often be sensitive to heat or radiation utilized for sterilization purposes. Since the capsule 12 can withstand conventional terminal sterilization techniques (see further below), it can be sterilized independently of the vial. This is a major advantage over many two-component syringe systems in which the components are separated only by some form of penetrable plug or diaphragm and must therefore either be fully assembled in a clean room, or subjected in assembled form to terminal sterilization techniques which may destroy or damage a component of the pharmaceutical preparation.

Where the capsule 12 is not being used, it is possible to utilize a cap 2 in which the needle 22 is not provided, and instead use a needle arrangement as shown in FIG. 13 or FIG. 15.

Features of presently most preferred embodiments of the invention are shown in FIGS. 13-15. The same reference numerals are used to denote the same parts in these figures as in the previous embodiments, where applicable, and construction and operation are similar except where otherwise indicated.

FIG. 13-15 show a further vial and syringe system according to the invention, the vial comprising a body 6 of rigid transparent material, usually glass although synthetic plastic resins might be utilized in certain applications. The body has the general configuration of a conventional vial except for the absence of a bottom wall. In order to compensate for the strengthening ef-

fect which would be provided by the bottom wall, in order to provide a detent for an optional plunger stabilizer ring 15 described further below, and in order to permit a slight flare at the extreme bottom end of the vial, a rounded bead 7 is provided around the perimeter of the bottom end of the body, although its peripheral extent should not be sufficient to increase substantially the diameter of the vial or decrease substantially its stability during handling.

A medicament A is retained within the vial by a piston 8. A closure 60 substantially fills a neck portion 67 of the vial after the vial, closed at the bottom by the piston, has been filled through its neck portion by a conventional vial filling machine. Although the medicament shown in a solid, it may be a liquid, or filled as a liquid and lyophilized to leave a solid residue. The piston 8 is moulded from rubber, preferably of at least 50 durometer hardness, and is formed with multiple, preferable three, peripheral ribs 81 on its outer surface, the external diameter of the ribs being slightly greater than the internal diameter of the body 6 so that an hermetic seal is established when the piston is pressed into the bottom of the body, initial entry being assisted by the flare mentioned above. The piston is moulded as a substantially solid body so that it has sufficient rigidity to maintain the desired hermetic seal with the body, any central bores within the piston (see FIG. 15) required to assist needle penetration being of insufficient radial extent to have any significant effect on its rigidity. Although in the piston shown in FIG. 16, a central bore 48 does just extend into the piston proper, its axial extent within the piston and its diameter are sufficiently small relative to the piston diameter that the rigidity of the piston is not substantially reduced. The longer bore 46 through the piston shown in FIG. 15 is of even smaller diameter so as not to prejudice piston rigidity.

The piston has a downward extension 18 of reduced diameter, in which the bore 48 is also present. The diameter of the bore 48 forms in this case a greater portion of the diameter of the extension 18, whose flexibility is thus somewhat increased by its presence. The extension carries on its outer surface a multistart thread, defined by grooves 16 which terminate abruptly short of the piston, forming abutments serving a purpose discussed further below. Provided that the hardness and rigidity requirements for the piston as a whole are met, the rubber utilized to form the piston, and any external coating on the rubber (which may act to increase the effective hardness of the rubber), are selected for compatibility with the medicament contained in the syringe, a number of approved materials being available and well known in the pharmaceutical art.

The neck closure 60 may be formed of similar rubber, and is similar in construction to that shown in FIGS. 9 and 10 if lyophilization of the syringe contents is required: otherwise the slot 63 and bores 62 (see FIG. 9) may be omitted. After insertion of the closure 60, its flange 64 may be held in place by a conventional cap 4 crimped over the flange and a flange on the neck of the bottle. Such a cap 4 may have a flip-off top attached to a separable central portion of the cap, partially severed from the remainder of the cap so that these portions may be broken away prior to assembly of the syringe to expose a central needle penetrable zone of the closure 60 above the bore 61.

The piston together with its extension 18 is relatively massive, with a weight which typically amounts to at least a major portion of that of the body 6. This weight in the lower part of the body assists in stabilising the vial during handling and filling and further inhibits tipping.

As mentioned above, vial assembly and filling will normally be performed in a clean room, since many pharmaceuticals will not withstand terminal sterilization procedures. The only additional step which requires to be carried out in the clean room other than is conventional in the filling of vials is the insertion of the piston 8.

In order to convert the basic vial into a syringe system, either one of two different approaches can be used, similar respectively to those described with reference to FIGS. 1 to 6 and FIGS. 11 and 12 above. Only the differences from that corresponding to FIGS. 1 to 6 will be described in detail for the present embodiment, since the differences from the system of FIGS. 11 and 12 arrangement will in general be similar. FIGS. 13 and 14 show the components of a syringe system separated, whilst FIG. 15 shown them assembled and sectioned (although an alternative needle arrangement is shown in FIG. 15). It should be understood that the diluent cartridge 14 and cartridge cap 12 are optional features of the system and will only be utilized when a diluent or solvent is required for the content of the vial which is not provided by some other means. When building a system similar to that shown in FIGS. 11 and 12, the same parts will be used, except that if the cartridge 14 and the cap 12 are used, the cap 12 will be modified in the manner illustrated in FIGS. 11 and 12. Assembly in the manner described with reference to FIGS. 11 and 12 has the advantages already described.

Referring to FIGS. 13 and 15, an outer cap 2 is pushed over the cap 4, and is similar to that shown in FIGS. 1, 2 and 12, except that the internal needle 22 shown in FIGS. 1 and 2 is omitted, the syringe being utilized with an alternative needle arrangement. In FIG. 13, a conventional double ended needle 28, is shown, the inner end of which replaces the needle 22.

FIG. 15 shows an arrangement in which the needle 28 may be single ended, an auxiliary hollow needle 35 being provided with a cylindrical sleeve 37 at the top which replaces the outer extremity of the inner portion of the coupling 27. A cap 39 is provided to retain the needle 35 within the coupling 27 until the needle 28 is fitted. When the syringe is to be used, the cap 39 is removed, and the sleeve of the needle is placed over the sleeve 37 and pushed down so that the needle 35 can penetrate the top of the vial and the needle 28 can be engaged with the coupling 27.

These needle arrangements are preferred for a syringe which is shipped in an essentially ready-to-use form, since the cap 2 may be pushed fully onto the cap 4 during assembly, yet the closure 60 remains unpenetrated until the needle (or other instrumentality as discussed below) is fitted at the time of use. On the other hand, the integral needle 22 is convenient where the assembly is to be utilized in the manner shown in FIGS. 11 and 12 and a capsule 12 is utilized. The inner surface of the cap 2 is provided with longitudinal ribs 23 which indent the soft aluminum of which the cap 4 is typically fabricated, and help retain the cap 2. The portions 41 and 43 of the cap 4, if present, are of course broken away prior to application of the cap 2.

The cap 4, closure 60, vial body 6 and piston 8 have already been described in detail above. The plunger 10 differs from that shown in FIGS. 1 and 2 in two respects. Its internal threads 20 end abruptly at abutments short of the front end of the plunger, so that when the

plunger is screwed onto the extension of the piston, the ends of the threads meet adjustments at the abutments at the ends of the external grooves on the extension, which grooves in this embodiment stop short of the inner end of the extension, just before the inner end of the plunger contacts the rear surface of the piston. This prevents the plunger being screwed excessively tightly against the back of the piston in a manner which might result in rocking movements of the plunger being transmitted directly to the piston. Instead such movements are largely absorbed by the flexibility of the extension 18. Secondly, the flange 26 at the rear end of the plunger is moulded so that about one half of its periphery is separated into an integral loop 11, which can be flexed rearwardly about hinge lines 13, and serves either as a thumb loop to assist manipulation of the syringe, or a suspension loop from which the syringe can be hung during infusion of its contents as discussed further below. The synthetic plastic material from which the plunger is moulded is selected from those having hinge forming capability such as many pharmaceutically acceptable grades of polypropylene.

In order to provide further stabilization of the plunger, to prevent its withdrawal from the body, and to provide a finger grip during manipulation of the syringe, particularly where longer vial bodies 6 are utilized, an optional plunger stabilizer and adapter ring 15 may be provided. This has axially extending inner flanges 150 which enter the inner end of the body, and retaining lugs 152, which snap over the bead 7. Openings 154 and flanges 156 may be provided on the rear surface of the ring, as required, to assist in adapting the syringe to infuser apparatus such as that shown in FIG. 8.

Where the contents of the vial are liquid and do not require reconstitution or dilution, or reconstitution is effected by a diluent or solvent introduced via a needle or cannula through the closure 60, the cartridge cap 12 and diluent cartridge 14 are not required, the components already described constituting a complete syringe system. Otherwise these components may be provided and utilized as already described in relation to the embodiments of FIGS. 1 to 6 or FIGS. 11 and 12. The components themselves are however somewhat modified as shown in FIG. 14, to facilitate handling. A skirt portion 120 of the cap is formed with longitudinal slots 122 extending from its rear edge, and inner lips 124 around the inner periphery of that edge, whilst a front extension of the cartridge 14 is provided with ribs 142 extending longitudinally between the peripheral ridges 36 and 38, which ribs are accommodated by the slots 22. The ribs 142 are continued beyond a peripheral groove behind the ridge 36. The threads 30 and the cap 12 are reduced to short ridges between certain of the slots 122. Because of the slots, the cap 12 is readily engaged over the ridge 38, but when the assembly is inserted into the interior of the plunger 10, the diameter of the cap relative to the internal chamber of the plunger 13 such that the lip 124 is pressed into the ring of shallow recesses defined between the ridges 36 and 38 and the ribs 142, thus ensuring that the threads 30 may be engaged with the threads 20 within the plunger by turning the capsule, and inhibiting accidental forward movement of the cartridge 14 into the cap 12. Further turning of the capsule drives the needle 44 forward into the bore 48 (see FIG. 14) and thence through a septum in the bore into a small diameter counterbore 46 through the head of the piston (similar to that shown in FIG. 2), a piston modified in this manner being utilized when a diluent cartridge is to be used. The cartridge can then be forced forward so that the lips 124 ride over the ridge 38, permitting the needle 42 to penetrate the capsule whose contents can then be transferred to the vial by squeezing and/or aspiration.

Provided that the cap 12 is provided with a coupling 70, the capsule can of course also be utilized as described with reference to FIGS. 11 and 12, in which case the passage 46 in the piston is not required.

The capsule 14 is blow moulded from a heat sealable, film grade, low melting, high ethylene random propyleneethylene copolymer suitable for medical use. An example of such a material, already approved for pharmaceutical applications, is DYPRO (trade mark) polypropylene Z9350 from Fina Oil and Chemical Company which has a melting point of about 130° C. Such a material, formed by injection of ethylene into a propylene matrix, combines necessary qualities of transparency, impermeability and flexibility with the stability to withstand sterilizing temperatures in an autoclave, despite its low melting point; the pressure in the autoclave is maintained at a sufficient level to prevent bursting of the capsule during sterilization. Conventional capsule materials are unsuitable for use in this application, since they lack at least one of the necessary properties of flexibility, transparency, impermeability, penetrability, compatibility with conventional pharmaceutical diluents, and ability to withstand sterilization temperatures without failure or degradation.

Utilization of syringes incorporating the above described modifications is similar to that of the other embodiments already described. The contents of the syringe may be delivered as already described with reference to FIGS. 6, 7 or 8, or in other ways. With a small modification to certain of the syringe components, the syringe contents may be reconstituted or diluted with fluid from an I.V. bag or minibag 160 and then injected into the bag for delivery, as shown in FIG. 16. Both the inner and outer components of coupling adaptor 27 of the cap 2 are elongated, and the bores of the inner component of the coupling adaptor and of the needle 22 are sufficient to provide an air venting passage around the read end of the needle 22 when fitted to the adaptor 27. A locking sleeve 29 on the needle 22, which sleeve engages the adaptor 27, is provided with a ventilation opening 31, such that when the sleeve 29 is screwed partially onto the adaptor as shown, air can escape through the sleeve as fluid from the bag 160 enters the syringe through the needle 22. When a desired amount of fluid has entered the syringe, the ventilation opening is closed by screwing the needle further onto the adaptor, following which the contents of the syringe may be injected into the bag 160.

The syringe of the invention is of course compatible with other syringe based drug administration systems.

I claim:

1. A vial formed of rigid transparent material and consisting of a cylindrical body, said body having an open bottom end having an external diameter at most only slightly greater than that of the remainder of the body, but sufficient relative to the height and center of gravity of the vial as a whole to support the latter in a stable manner when conveyed standing on its open end through vial filling and capping machinery, injectable material within the body, comparatively wide neck at the top of the body through which said injectable material is filled into the body, an external peripheral flange

surrounding the neck, an elastomeric closure applied to the neck, a cylindrical cap clamped onto the flange of the neck and having an annular inward extending flange at a top end overlapping the closure to secure the closure to the neck with the closure presenting a needle penetrable central portion, an impervious substantially solid piston of resilient material scalingly received within said body at its lower end beneath said injectable material and above said open bottom end, and a flexible reduced diameter extension integral with said piston, projecting downwardly from said piston but wholly within the body, for establishing a flexible connection to a syringe plunger in a zone between the piston and said open end of the body, whereby said vial may be converted into a syringe for ejection of the injectable material on movement of the piston towards the neck, by connection of said syringe plunger to said extension and connection of fluid conduit coupling means to said cylindrical cap, wherein the piston and its extension are formed of rubber of at least 30 durometer hardness, and the extension is formed with a central bore to increase its flexibility.

2. A vial according to claim 1, wherein the piston is formed with multiple axially spaced peripheral ribs in compressive engagement with an inside cylindrical wall of the vial body.

3. A syringe comprising a vial according to claim 1, an outer cap which is a push fit over the cap of the vial and incorporates a needle mounting adaptor concentric with said needle penetrable portion of the closure, and a tubular cylindrical syringe plunger for coupling to said flexible extension of the piston.

4. A syringe according to claim 3, further including an inwardly directed hollow needle received within the needle mounting adaptor, and a sleeve secured to an outer end of the needle projecting beyond the adaptor such that pressure on the sleeve when an injection needle is coupled to the adapter will force the hollow needle through the needle penetrable portion of the closure of a vial to which the outer cap is applied.

5. A vial formed of rigid transparent material and consisting of a cylindrical body, said body having an open bottom end having an external diameter at most only slightly greater than that of the remainder of the body, but sufficient relative to the height and center of gravity of the vial as a whole to support the latter in a stable manner when conveyed standing on its open end through vial filling and capping machinery, injectable material within the body, a comparatively wide neck at the top of the body through which said injectable material is filled into the body, an external peripheral flange surrounding the neck, an elastomeric closure applied to the neck, a cylindrical cap clamped onto the flange of the neck and having an annular inward extending flange at a top end overlaying the closure to secure the closure to the neck with the closure presenting a needle penetrable central portion, an impervious substantially solid piston or resilient material scalingly received within said body at its lower end beneath said injectable material and above said open bottom end, and a flexible reduced diameter extension integral with said piston, projecting downwardly from said piston but wholly within the body, for establishing a flexible connection to a syringe plunger in a zone between the piston and said open end of the body, whereby said vial may be converted into a syringe for ejection of the injectable material on movement of the piston towards the neck, by connection of said syringe plunger to said extension and connection of fluid conduit coupling means to said cylindrical cap; wherein the extension is formed with external screw threads for engagement with complementary threads on the plunger, and with abutment means to limit the distance through which the plunger can be screwed onto said threads, such as to prevent rigid abutment of the plunger against the piston and to enable the extension to form a flexible connection between the plunger and the piston.

6. A vial formed of rigid transparent material and consisting of a cylindrical body, said body having an open bottom end terminating in a peripheral bead having an external diameter at most only slightly greater than that of the remainder of the body, but sufficient relative to the height and center of gravity of the vial as a whole to support the latter in a stable manner when conveyed freestanding on said bead through vial filling and capping machinery, injectable material within the body, a comparatively wide neck at the top of the body through which said injectable material is filled into the body, an external peripheral flange surrounding the neck, an elastomeric closure applied to the neck, a cylindrical cap clamped onto the flange of the neck and having an annular inward extending flange at a top end overlaying the closure to secure the closure to the neck with the closure presenting a needle penetrable central portion, an impervious substantially solid piston of resilient material scalingly received within said body at its lower end beneath said injectable material and above said bead, and a flexible reduced diameter extension integral with said piston, projecting downwardly from said piston but wholly within the body, for establishing a flexible connection to a syringe plunger in a zone between the piston and said open end of the body, whereby said vial may be converted into a syringe for ejection of the injectable material on movement of the piston towards the neck, by connection of said syringe plunger to said extension and connection of fluid conduit coupling means to said cylindrical cap, wherein the weight of the piston and its extension is at least a major portion of that of the vial body, and the height of the vial body does not exceed about 2.5 times the external diameter of the bead.

7. A vial formed of rigid transparent material and consisting of a cylindrical body, said body having an open bottom end having an external diameter at most only slightly greater than that of the remainder of the body, but sufficient relative to the height and center of gravity of the vial as a whole to support the latter in a stable manner when conveyed standing on its open end through vial filling and capping machinery, injectable material within the body, a comparatively wide neck at the top of the body through which said injectable material is filled into the body, an external peripheral flange surrounding the neck, an elastomeric closure applied to the neck, a cylindrical cap clamped onto the flange of the neck and having an annular inward extending flange at a top end overlaying the closure to secure the closure to the neck with the closure presenting a needle penetrable central portion, an impervious substantially solid piston of resilient material scalingly received within said body at its lower end beneath said injectable material and above said open bottom end, and a flexible reduced diameter extension integral with said piston, projecting downwardly from said piston but wholly within the body, for establishing a flexible connection to a syringe plunger in a zone between the piston and said open end of the body, whereby said vial may be converted into a

syringe for ejection of the injectable material on movement of the piston towards the neck, by connection of said syringe plunger to said extension and connection of fluid conduit coupling means to said cylindrical cap,

wherein the closure substantially fills the neck of the body, and has a top flange overlying the neck and defines a central bore extending from the bottom of the closure to a point beneath said needle penetrable central portion, and wherein the closure further defines a cross bore extending from an outer wall of the closure beneath the flange to said central bore, whereby said cross bore and said central bore together constitute a vent from the interior of the vial when the closure is partially inserted in the neck of the vial body.

8. A syringe comprising:

A vial formed of rigid transparent material and consisting of a cylindrical body, said body having an open bottom end terminating in a peripheral bead having an external diameter at most only slightly greater than that of the remainder of the body, but sufficient relative to the height and center of gravity of the vial as a whole to support the latter in a stable manner when conveyed freestanding on said bead through vial filling and capping machinery, injectable material within the body, a comparatively wide neck at the top of the body through said injectable material is filled into the body, an external peripheral flange surrounding the neck, an elastomeric closure applied to the neck, a cylindrical cap clamped onto the flange of the neck and having an annular inward extending flange at a top end overlying the closure to secure the closure to the neck with the closure presenting a needle penetrable central portion, an impervious substantially solid piston of resilient material sealingly received within said body at its lower end beneath said injectable material and above said bead, and a flexible reduced diameter extension integral with said piston, projecting downwardly from said piston but wholly within the body, for establishing a flexible connection to a syringe plunger in a zone between the piston and said open end of the body, whereby said vial may be converted into a syringe for ejection of the injectable material on movement of the piston towards the neck, by connection of said syringe plunger to said extension and connection of fluid conduit coupling means to said cylindrical cap;

an outer cap which is a push fit over the cap of the vial and incorporates a needle mounting adaptor concentric with said needle penetrable portion of the closure; and

a syringe plunger for coupling to said flexible extension of the piston, wherein a tubular cylindrical front end of the syringe plunger is press fitted onto a front end of the outer cap to form a separately sterilized subassembly.

9. A syringe, comprising:

A vial formed of rigid transparent material and consisting of a cylindrical body, said body having an open bottom end terminating in a peripheral bead having an external diameter at most only slightly greater than that of the remainder of the body, but sufficient relative to the height and center of gravity of the vial as a whole to support the latter in a stable manner when conveyed freestanding on said bead through vial filling and capping machinery, injectable material within the body, a comparatively wide neck at the top of the body through which said injectable material is filled into the body, an external peripheral flange surrounding the neck, an elastomeric closure applied to the neck, a cylindrical cap clamped onto the flange of the neck and having an annular inward extending flange at a top end overlaying the closure to secure the closure to the neck with the closure presenting a needle penetrable central portion, an impervious substantially solid piston of resilient material sealingly received within said body at its lower end beneath said injectable material and above said bead, and a flexible reduced diameter extension integral with said piston, projecting downwardly from said piston but wholly within the body, for establishing a flexible connection to a syringe plunger in a zone between the piston and said open end of the body, whereby said vial may be converted into a syringe for ejection of the injectable material on movement of the piston towards the neck, by connection of said syringe plunger to said extension and connection of fluid conduit coupling means to said cylindrical cap;

an outer cap which is push fit over the cap of the vial and incorporates a needle mounting adaptor concentric with said needle penetrable portion of the closure; and

a syringe plunger having a tubular cylindrical end portion for coupling to said flexible extension of the piston;

wherein a piston stabilizer ring is a snap fit on the bead, the piston stabilizer ring having flanges extending into the vial body between the inner wall of the body and the plunger to limit tilting of the plunger and prevent withdrawal of the piston from the body.

10. A syringe comprising a vial formed of rigid transparent material and consisting of a cylindrical body, said body having an open bottom end having an external diameter at most only slightly greater than that of the remainder of the body, but sufficient relative to the height and center of gravity of the vial as a whole to support the latter in a stable manner when conveyed standing on its open end through vial filling and capping machinery, injectable material within the body, a comparatively wide neck at the top of the body through which said injectable material is filled into the body, an external peripheral flange surrounding the neck, an elastomeric closure applied to the neck, a cylindrical cap clamped onto the flange of the neck and having an annular inward extending flange at a top end overlaying the closure to secure the closure to the neck with the closure presenting a needle penetrable central portion, an impervious substantially solid piston of resilient material sealingly received within said body at its lower end beneath said injectable material and above said open bottom end, and an extension integral with said piston, projecting downwardly from said piston but wholly within the body, a needle mounting adaptor concentric with said needle penetrable portion of the closure, and an elongated syringe plunger for coupling to said flexible extension of the piston;

wherein the syringe plunger is moulded from synthetic plastic having hinge-forming capability, and has an outwardly extending flange at its rear end, a peripheral portion of this flange being separated form the remainder around about half of its circum-

ference, and the ends of the separated portion being connected to the remainder by integrally formed hinges to form a loop which can be pulled rearwardly of the flange.

11. A syringe plunger comprising an elongated stem defining a cylindrical recess at one end moulded from synthetic plastic material having hinge-forming capability, a cylindrical rubber piston of greater diameter than the plunger, an axial extension at one end of the piston entering within and releasably engaged with said cylindrical recess at one end of the plunger, and an outwardly extending flange at the other end of the plunger, a peripheral portion of this flange being separated from the remainder around about half of its circumference, and the ends of the separated portion being connected to the remainder by integral hinge-forming bridges to form a loop which can be pulled rearwardly of the flange.

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United States Patent [19]

Turley

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[45] **Date of Patent: Jul. 1, 1986**

[54] **IMPLANTING METHOD AND DEVICE**

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[73] Assignee: Hundon Forge Limited, Haverhill, England

[21] Appl. No.: 601,998

[22] Filed: Apr. 18, 1984

[30] **Foreign Application Priority Data**

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Aug. 4, 1983 [GB] United Kingdom 8320993

[51] Int. Cl.⁴ A61M 5/18
[52] U.S. Cl. 604/61
[58] Field of Search 604/60, 59, 61–64

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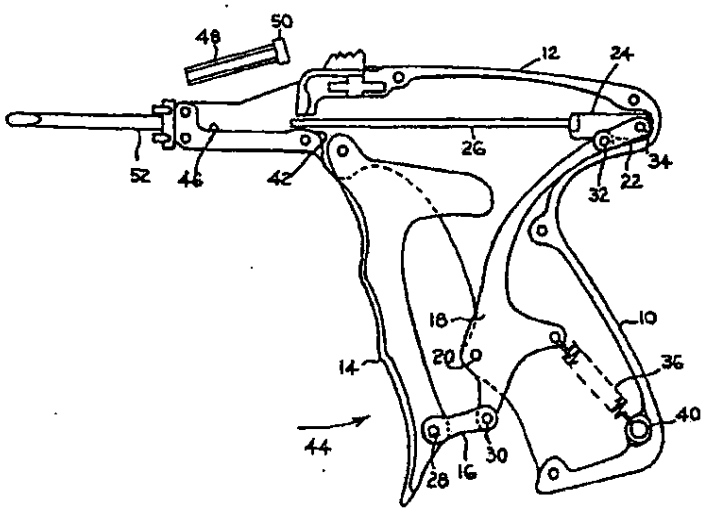
[57] **ABSTRACT**

An implanter for implanting treatment pellets beneath the skin of animals comprises a hollow needle (52) through which a drive pin (26) is displaceable to drive a pellet (64) through the needle and in use to a controlled depth below the skin. A forked abutment (54) straddles the needle, being spring urged into a normal location near the rear end of the needle. The abutment (54) is carried by a rearwardly extending rod (56) having a drive member (62) engagable by a thrust member (63) on the drive pin during part of the forward movement of the latter. In use, when the abutment member is against the animal being treated, the final part of the forward movement of the drive pin effects a retraction of the needle, leaving the pellet implanted at the correct depth (FIGS. 4 to 6).

9 Claims, 7 Drawing Figures



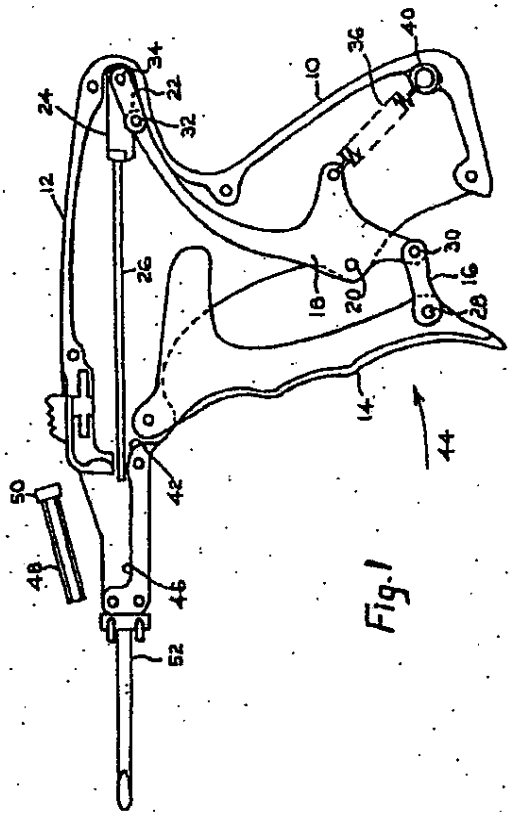


Fig. 1

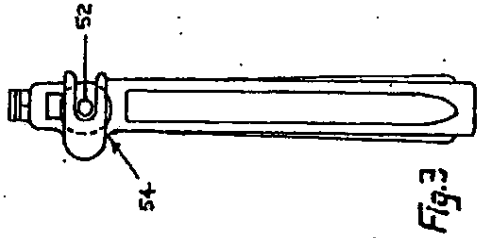


Fig.3

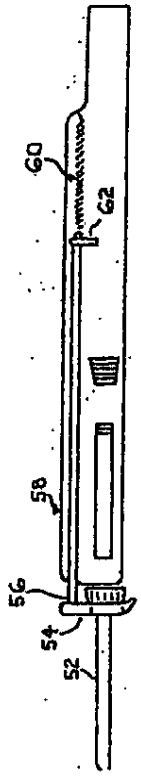


Fig.2

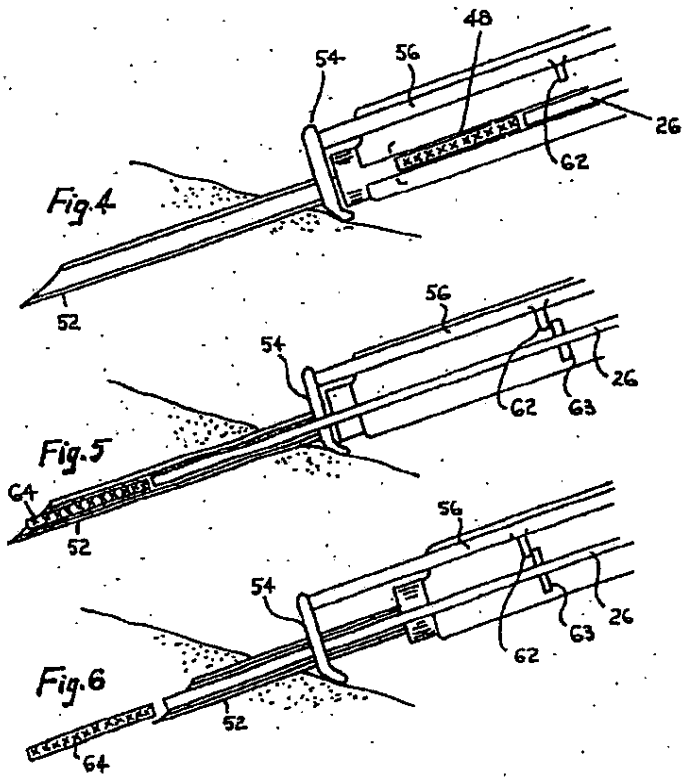


Fig.4

Fig.5

Fig.6

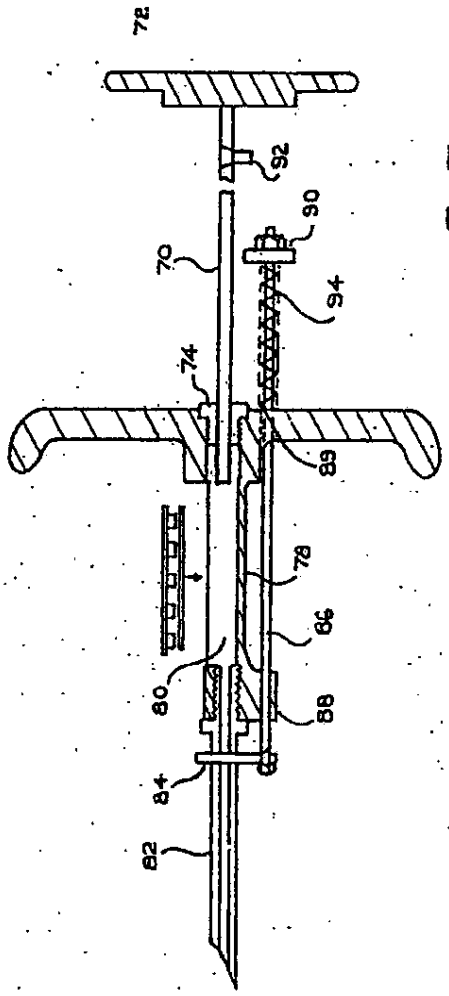


Fig. 7

IMPLANTING METHOD AND DEVICE

DESCRIPTION

1. Field of Invention

This invention concerns an improved method and device for implanting pelletted drugs and other chemicals below the skin of an animal. The invention is particularly adaptable to hand-held implanter to facilitate the accurate location of one or more pellets below the skin.

2. Background to the Invention

It has been found that pelletted drugs and other chemical compounds will sometimes be rejected by an animal after implantation. Although all of the reasons for such rejection are not clearly established, it is clear that one of the contributory causes to a high rejection rate is placement of the pellet or pellets at an inadequate depth below the surface of the skin.

Clearly it is not desirable to inject the pellets too deeply into the animal since it is essential that the pellets are held in the fatty tissues adjacent the skin into which the chemical material and drugs will be absorbed. On the other hand, it is clear from observation that if the pellet or pellets are left just below the surface of the skin and effectively in the wound formed by the insertion of a hypodermic syringe needle, the pellet or pellets will be seen by the animal as a foreign body and will be rejected and the pellets will sometimes appear as a source of local infection and irritation to the animal before rejection.

It is an object of the present inveation to provide an improved implanter to facilitate the implantation of pelletted materials at a correct depth below the surface of the skin so that an improvement can be obtained in the implant rejection rate which can otherwise arise.

THE INVENTION

According to the present invention, in an improved device for implanting pelletted material below the skin of an animal comprising:

1. an operating mechanism such as a gun-type body member including a trigger or a plunger-type mechanism;
2. a hollow needle protruding therefrom for insertion into the skin of an animal through which pelletted material can be forced; and
3. a pin adapted to be moved by the operating mechanism in a forward direction to urge pelletted material into the rear of the needle and through the same into the animal, and the improvement comprising:
   (1) an abutment member movable relative to the shank of the needle and normally located at or adjacent the junction of the needle and the operating mechanism and,
   (2) means for moving the said abutment member relative to the needle shank away from the said junction towards the tip of the needle in response to at least part of a forward movement of the implant pin to assist in the accurate placement of an implant relative to the surface of the skin.

Preferably the drive to the said abutment member is effected by means of a thrust member carried by the pin (or movable in response to movement of the pin) which in turn acts upon a member attached to the rear of the said abutment member to urge the abutment member in a forward direction.

By adjusting the position of the thrust member on, or relative to the motion of, the pin, the point at which the abutment member will begin to move can be controlled.

Preferably, means is provided for adjusting this parameter so that different sized implants can be accommodated and/or different sized needles can be accommodated.

According to a preferred feature of the invention, the thrust member is adapted to engage the member protruding from the rear of the abutment at the point at which a pelletted implant just reaches the end of the needle.

In use, the device is held adjacent an animal's skin and the sharp end of the needle is forced into the skin until the abutment member at or adjecent the junction of the needle shank and operating mechanism just comes into contact with the skin. At that stage the operating mechanism is squeezed and the implanting pin is moved in a forward direction so as to urge the implant down the hollow interior of the needle. As the pelletted implant reaches the end of the needle and begins to enter the flesh of the animal, the thrust member associated with the pin makes contact with the member protruding from the rear of the said abutment which straddles the needle and continued squeezing movement of the operating mechanism will cause the needle attached to move in a rearward direction away from the abutment member. By keeping the abutment member in contact with the skin of the animal, the net effect is that the needle is withdrawn rearwardly leaving the pin at the same depth which, in turn, prevents the pelleted implant from being dragged back by the rearwardly moving needle. At the point of maximum travel of the operating machanism, the needle will have just cleared the rear end of the pelletted implant and withdrawal of the device in a rearward direction, pulling the needle out of the flesh, will leave the implant firmly embedded in the flesh at the desired depth.

Note that the depth at which the implant is left will be governed by the point at which the abutment begins to move the needle in a rearward direction with continued squeezing of the operating mechanism, provided the latter can accommodate a sufficient relative movement of pin and needle.

Preferably, spring means is provided urging the abutment in a rearward direction (i.e. towards the junction between the needle and the body of the operating member) so that when the trigger mechanism is released, the abutment moves back to its normal rest position.

In the same way, spring means is preferably provided to return the pin to its home position well clear and to the rear of the breech into which the implants are placed for injection, so that as soon as the operating mechanism is released, the pin will return to its home position.

The invention allows a relatively unskilled person to successfully and consistently implant drugs or like materials at a constant depth below the surface of the skin of an animal. The method is considerably simpler and more reliable than previous methods which have required the needle to be manually withdrawn while the operating mechanism is kept squeezed. In general, previous methods and devices have required a high degree of skill if the implant was not to be accidentally left too close to the surface of the skin at an insufficient depth thereby causing rejection or damage to the implant by crushing.

According to a preferred development of the invention, the needle mounting within a gun-shaped body member may itself be displacable rearwardly against return spring means so that, as the abutment is engaged by the thrust member of the advancing pin, the needle is automatically withdrawn in a rearward direction by continued squeezing action of the trigger mechanism without rearward movement of the gun-shaped body. This refinement clearly simplifies the action of implanting a pellet or pellets below the surface of the skin since the only skill required is to pierce the skin with the sharp end of the hollow needle and push the needle into the animal to the depth at which the abutment just makes contact with the skin whereafter a gentle squeezing action on the trigger mechanism will result in completely automatic disposal of the implant into the animal and withdrawal of the needle at least to the point at which the complete mechanism can be pulled out of the animal without any need for forward or rearward movement of the "gun" whatsoever.

The invention also lies in a method of implanting one or more pellets of a chemical such as a drug at a controlled depth below the skin of an animal comprising the steps of:

1. piercing the animal's skin with a hollow needle having a displacement abutment member associated therewith;
2. forcing by means of an advancing pin, the material to be implanted, through the hollow interior of the needle;
3. at or near the point at which the implant material is ejected from the hollow needle, effecting relative movement between the needle and an abutment member in contact with the surface of the animal's skin so that continued operation of the mechanism effecting forward movement of the implanting pin will effect withdrawal of the hollow needle around the pin if the abutment is kept in contact with the skin; and,
4. after the complete travel of the operating mechanism has been effected and the implant material is left fully clear of the rearwardly moving needle, removing the needle and pin from the animal.

Where the needle is rigidly attached to the body of the planting device, a rearward movement of the latter must be accommodated by the operator after the relative movement between the abutment and needle becomes effective.

Where relative movement between the needle and the body of the hand-held implanting device is permissible, no rearward movement of the device is necessary except to withdraw the needle at the end of the stroke and all of the movements to effect implantation are effected by the relative movements of the pin and needle and abutment.

The invention will now be described by way of reference to the accompanying drawings in which:

FIG. 1 is a side view of an implanter embodying the invention;

FIG. 2 is a top view of the implanter shown in FIG. 1;

FIG. 3 is a front view of the implanter in FIG. 1 looking from the left of the view shown in FIG. 1;

FIG. 4 illustrates to a larger scale the initial insertion of the needle into the flesh of an animal;

FIG. 5 is a similar view to that of FIG. 4 at an intermediate stage during the implanting process;

FIG. 6 illustrates the final stage of implantation just before the needle is withdrawn; and

FIG. 7 illustrates an alternative construction of implanter incorporating the invention.

DETAILED DESCRIPTION OF THE DRAWINGS

FIG. 1 shows an implant gun comprising handle 10 and body section 12 and hinged trigger 14. The latter acts on a pivoted mechanism made up of a short arm 16, a long arm 18 pivoted at 20, a second short arm 22 and a pin mount 24 from which an implanting pin 26 extends.

The short arms 16 and 22 are themselves pivoted to the trigger 14 at 28 and to the lower end of the long arm 18 at 30 and to the upper end of the long arm 18 at 32 and to the pin mount 24 at 34, respectively.

A spring 36 extends between a rearwardly extending protrusion of the long arm 18 and a fixing 40 at the lower rear of the handle 10.

A guide 42 is provided in the front end of the body 12 through which the forward end of the pin 26 just protrudes when the pin amount 24 is at the rear of the body 12.

A squeezing of the trigger 14 in the direction of the arrow 44 results in a forward movement of the pin 26.

In front of the body member 12 is a breech or implant chamber 46 into which cylindrical cartridges such as 48 containing one or more pellets 64 of drug or other chemical can be fitted so that the axis of the cylindrical cartridge such as 48 is aligned with the axis of the pin 26.

The implant cartridges are typically formed with an enlarged head at one end such as at 50 so as to prevent the cartridge from being inserted into the implant chamber 46 incorrectly.

The forward end of the implant chamber is an exit passage (not shown) which communicates with the interior of a hollow needle 52 through which the pellets 64 can be forced in advance of the pin 26 upon forward movement of the latter.

The stroke of the pin 26 is arranged to be such that the leading end of the pin can move from the rear of the breech 46 to the forward end of the needle 52.

As best seen in FIGS. 2 and 3, a bifurcated fork or abutment member 54 straddles the needle 52 and is mounted at the front end of a rod 56 which is guided in a lateral guide 58 on one side of the main body 12. Forward movement of the rod 56 results in corresponding forward movement of the fork 54.

The rod 56 is held urged in a rearward direction so that the forked abutment 54 sits snugly against the leading end of the body 12, by means of a spring 60 located at the end of the guide 58.

Forward movement of the forked abutment 54 is effected by a thrust member 62 which extends laterally from a point at or towards the rearward end of the rod 56 and is engagable by a thrust engaging member 63 (see FIG. 5) such as a disc or pin located near the rearward end of the pin 26. Relative positioning of the latter and/or the thrust member 62 along the length of the rod 56, controls the point at which the forked abutment member 54 will first be moved in a forward direction as the pin 26 is urged forwardly.

Forward movement of the rod 56 results in the spring 60 becoming stretched as the abutment member 54 and rod 56 will move in a rearward direction when the trigger 14 is released, under the restoring force of the stretched spring 60.

Although not shown, means is provided for adjusting the position of the thrust member 62 and the disc or other thrust engaging member 63 (Fig. 5) carried by or located on the pin 26.

It is to be understood that the pin mounting 24 may itself constitute or form a support for the thrust engaging member 63 for engaging the thrust member 62.

FIG. 3 shows how the bifurcated forked abutment member 54 straddles the needle 52.

FIGS. 4, 5 and 6 illustrate how the improvement operates in practice.

Initially, the gun is located with the sharp end of the needle against the skin of the animal with an implant cartridge 78 in position. The gun is moved swiftly in a forward direction piercing the skin so that the needle occupies the position shown in FIG. 4 with the forked abutment just touching the skin.

The trigger 14 is then squeezed until the intermediate position is reached at which the material which is to be implanted (shown as a single large pellet, but possibly made up of a number of pellets one behind the other) and designated by reference numeral 64, just reaches the end of the needle 52. At this point the abutment thrust engaging member 63 on the pin 26 (or the mount 24) just engages the thrust member 62. continued squeezing of the trigger 14 will effect relative movement of the abutment 54 and needle 52 and an effective withdrawal of the needle over the pin leaving the pellet 64 firmly embedded at controlled depth.

Although not shown, the needle may be mounted for movement relative to the gun so that the latter can be held stationary until the end.

FIG. 7 shows an alternative embodiment of pellet implanter having a plunger type operating mechanism.

A drive pin 70, terminated at the rear by a pressure plate 72 to be pressed by the palm of the hand, extends forwardly through a guide 74 in a finger grip 76. The latter is disposed at the rear end of a body 78 which has a pellet-cartridge-receiving chamber 80 behind a hollow needle 82.

By squeezing the palm plate 72 towards the finger grip 76, the rod can be displaced through the chamber 80 and into and through the needle 82, driving a pellet in front of it.

A forked abutment 84 is disposed around the needle 82 towards the rear end thereof, being carried at the front end of a rod 86 which extends rearwardly through a front guide 88 and a rear guide 89 carried by the finger grip 76. At its rear end, the rod 86 carries a drive member 90 engagable by a thrust member 92, such as a thrust ring, on the drive pin 70, thereby to enable pellet implantation i the manner previously described with reference to FIGS. 4 to 6.

A return spring 94 acts between the finger grip 76 and the rod drive member 90, thereby to urge the forked abutment 84 towards its normal position adjacent the rear end of the needle 82.

An implanter as illustrated in FIG. 7 may be fully machined or metal die cast, or it can be inexpensively moulded of plastics material for short-lived usage.

I claim:

1. A pellet implanter for the injection of animals, comprising:

a body member,

a hollow needle extending from one end of the body member,

a pin slidably received in the needle and forwardly movable through the needle to urge pelleted material through said needle and into the animal;

an operating mechanism for driving the pin, the mechanism carried by the body member,

abutment means movably mounted on the body member and located outside and adjacent to the needle, said abutment means being movable relative to the shank of the needle in the longitudinal direction thereof and normally being positioned remote from the needle tip; and

means establishing a coupling between the abutment means and the pin for moving the abutment means relative to the needle shank towards the needle tip in response to at least part of the forward movement of the pin.

2. An implanter according to claim 1, wherein the abutment means is movable by means of a thrust member drivable by the pin and which, during forward movement of the pin, is brought into engagement with a drive member coupled to the abutment means.

3. An implanter according to claim 1, wherein the abutment means is spring urged rearwardly into its normal position remote from the needle tip.

4. An implanter according to claim 1 wherein the operating mechanism is spring loaded to urge the pin towards its rearmost position.

5. An implanter according to claim 1, including a breech chamber open or openable to receive a pellet when the pin is in its rearmost position.

6. An implanter according to claim 1, wherein the needle is carried by a mounting which is displacable rearwardly, against a return spring, relative to the operating mechanism.

7. An implanter according to claim 1, wherein the operating mechanism comprises a gun-like body including a trigger mechanism.

8. An implanter according to claim 1, wherein the operating mechanism comprises a syringe-type plunger carrying the pin.

9. A method of implanting pellets at a controlled depth below the skin of an animal, the method comprising the steps of:

(a) piercing the animal's skin with a hollow needle having a displacement abutment member associated therewith;

(b) forcing by means of an advancing pin, the material to be implanted, through the hollow interior of the needle after the latter has been pushed into the animal to a depth sufficient to bring the abutment member into contact with the skin;

(c) adjacent the point at which the implant material is ejected from the hollow needle, effecting relative movement between the needle and the abutment member in contact with the surface of the animal's skin so that continued operation of the mechanism effecting forward movement of the implanting pin will effect withdrawl of the hollow needle around the pin if the abutment is kept in contact with the skin; and

(d) after the complete travel of the operating mechanism has been effected and the implant material is left fully clear of the rearwardly moving needle, removing the needle and pin from the animal.

* * * * *

Attorney Docket No.: 5637.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Application No.: 09/348,536 Group Art Unit: 3734

Filed: July 7, 1999 Examiner: To be assigned

For: Medication Delivery Device

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, DC 20231

#9 AMB 6/12/00

Sir:

In accordance with 37 C.F.R. 1.56, 1.97 and 1.98, Applicants submit herewith references which they believe may be material to the patentability of this application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. 1.56.

While the references may be "material" under 37 C.F.R. 1.56, it is not intended to constitute an admission that the references are "prior art" unless specifically designated as such.

The filing of this Information Disclosure Statement shall not be construed as a representation that no other material references than those listed exist or that a search has been conducted.

The references are listed in PTO form 1449 which is in accordance with the requirements of M.P.E.P. 609. A copy of the references is also enclosed. The references are as follows:

1. EP 0 688 571
2. U.S. 4,936,833
3. U.S. 5,226,895
4. U.S. 5,549,575
5. U.S. 5,688,251
6. WO 95/13842

7. WO 94/21213
8. WO 97/49620
9. WO 96/02290
10. U.S. 4,973,318

It is respectfully requested that these references be considered by the Patent and Trademark Office in its examination of the above-identified application and be made of record therein. The Examiner is also invited to contact the Undersigned if there are any questions concerning this paper or the attached references.

Respectfully submitted,

Date: January 26, 2000

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FORM PTO-1449 (MOD.)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

Atty. Docket No. 5637.200-US	Serial No. 09/348,536
Applicant Buch-Rasmussen et al.	
Filing Date July 7, 1999	Group 3734

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
KCS		4,936,833	6/26/90	Sams	✓	✓	
		5,226,895	7/13/93	Harris	✓	✓	
		5,549,575	8/27/96	Giambattista et al.	✓	✓	
		5,688,251	11/18/97	Chanoch	✓	✓	
✓		4,973,318	11/27/90	Holm et al.	✓	✓	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
KCS		EP 0 688 571	12/27/95	EPO	✓	✓		
		WO 95/13842	5/26/95	WIPO	✓	✓		
		WO 94/21213	9/29/94	WIPO	✓	✓		
		WO 97/49620	12/31/97	WIPO	✓	✓		
✓		WO 96/02290	2/1/96	WIPO	✓	✓		

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER Simmons DATE CONSIDERED 11/6/01

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

United States Patent [19]

Sams

[11] **Patent Number: 4,936,833**

[45] **Date of Patent: Jun. 26, 1990**

[54] **CARTRIDGE-HOLDER ASSEMBLY FOR MEDICATION DISPENSING UNIT**

[75] Inventor: **Bernard Sams, London, England**

[73] Assignee: **Hypoguard (UK) Limited, Woodbridge, England**

[21] Appl. No.: **237,147**

[22] Filed: **Aug. 26, 1988**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 205,198, Jun. 10, 1988, Pat. No. 4,865,591, which is a continuation-in-part of Ser. No. 81,241, Aug. 4, 1987, abandoned.

[51] Int. Cl.[5] A61M 5/24

[52] U.S. Cl. 604/232; 604/208; 604/209; 604/220; 222/391

[58] Field of Search 604/68, 72, 208–210, 604/218, 220, 232, 234, 197; 222/325, 340, 391

[56] **References Cited**

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FOREIGN PATENT DOCUMENTS

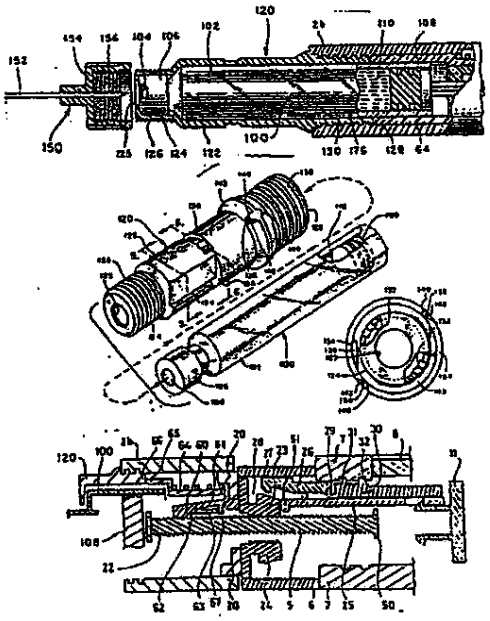
22140	10/1961	German Democratic Rep.	222/391

Primary Examiner—Martin P. Schwadron
Assistant Examiner—Allen J. Flanigan
Attorney, Agent, or Firm—Willian Brinks Olds Hofer Gilson & Lione

[57] **ABSTRACT**

A cartridge assembly for a syringe-type medication dispensing unit includes a cartridge having a cartridge body with first and second ends. A pierceable membrane is mounted at the first end and a piston is mounted at the second end, with a volume of medication contained in the cartridge body between the membrane and the piston. A cartridge holder receives the cartridge and defines first and second ends. The first holder end defines a central opening and an external thread for mounting a double-ended needle. The second holder end defines an external thread for securing the holder to a medication dispensing unit and an actuating shoulder. The holder frictionally engages the cartridge to form an assembly which can be handled as a single modular unit with the cartridge held securely in the holder by frictional engagement.

23 Claims, 6 Drawing Sheets



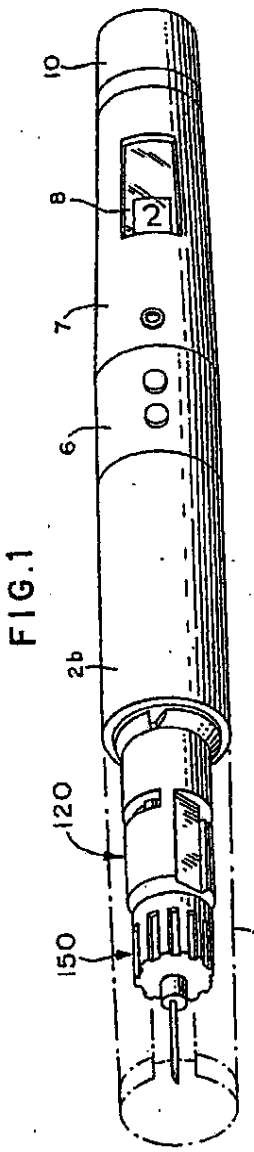

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FIG. 1

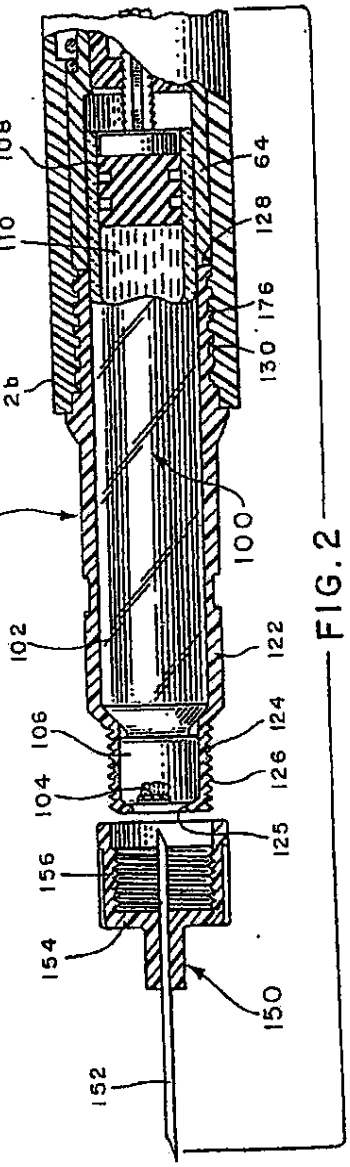
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FIG. 2

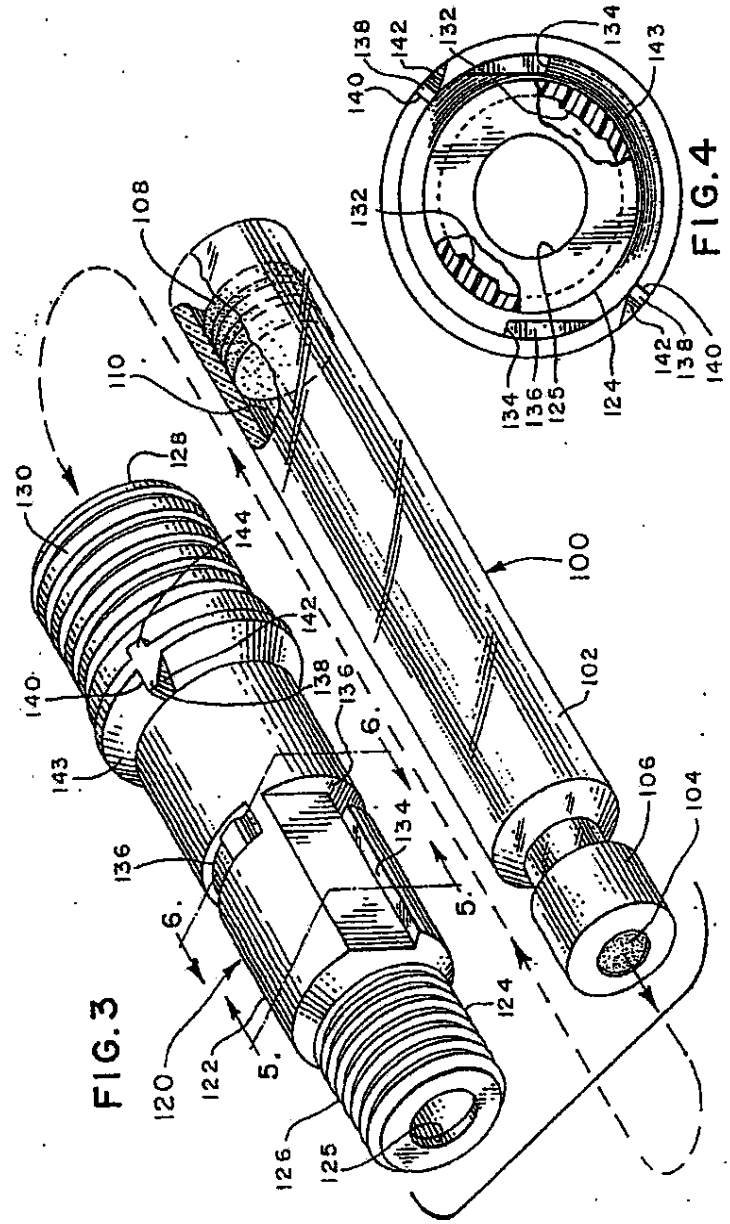
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FIG. 3

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FIG. 4

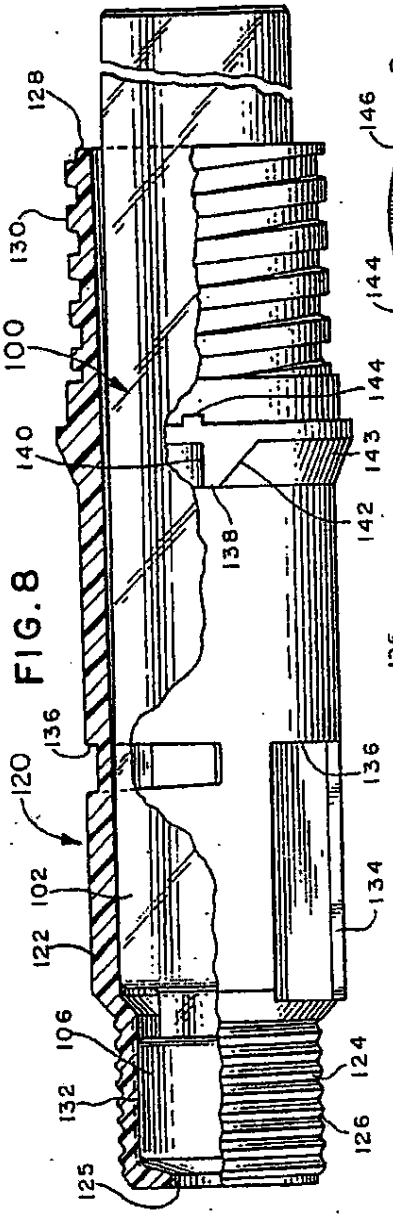


FIG. 8

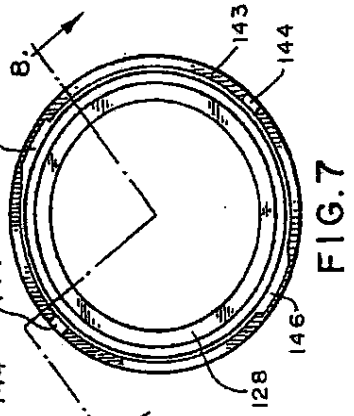


FIG. 7

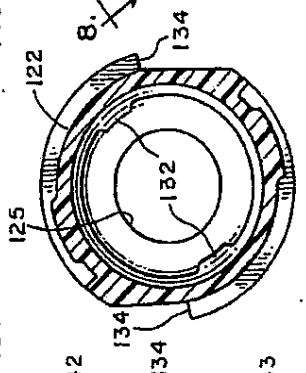


FIG. 6

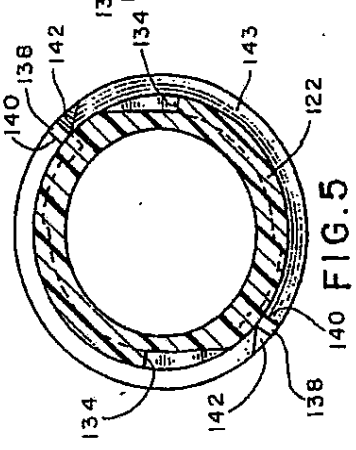


FIG. 5

FIG.9

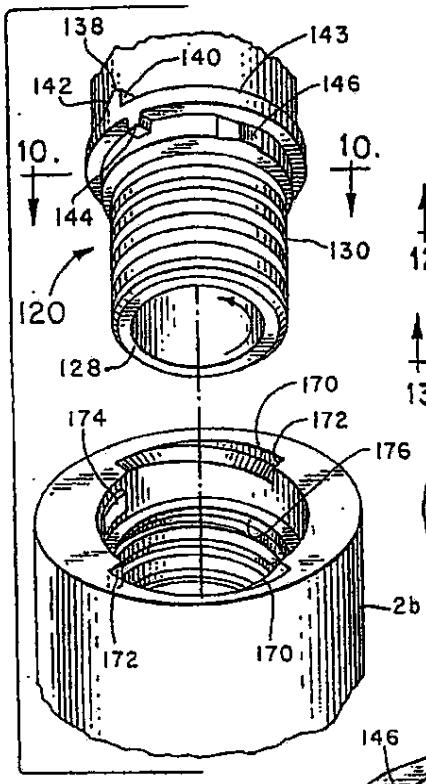
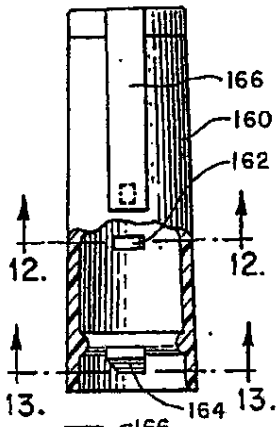


FIG.11



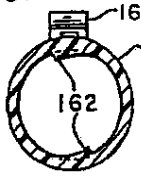


FIG.12

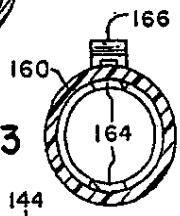


FIG.13

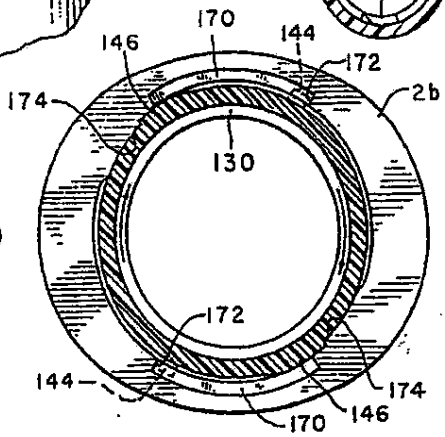


FIG.10

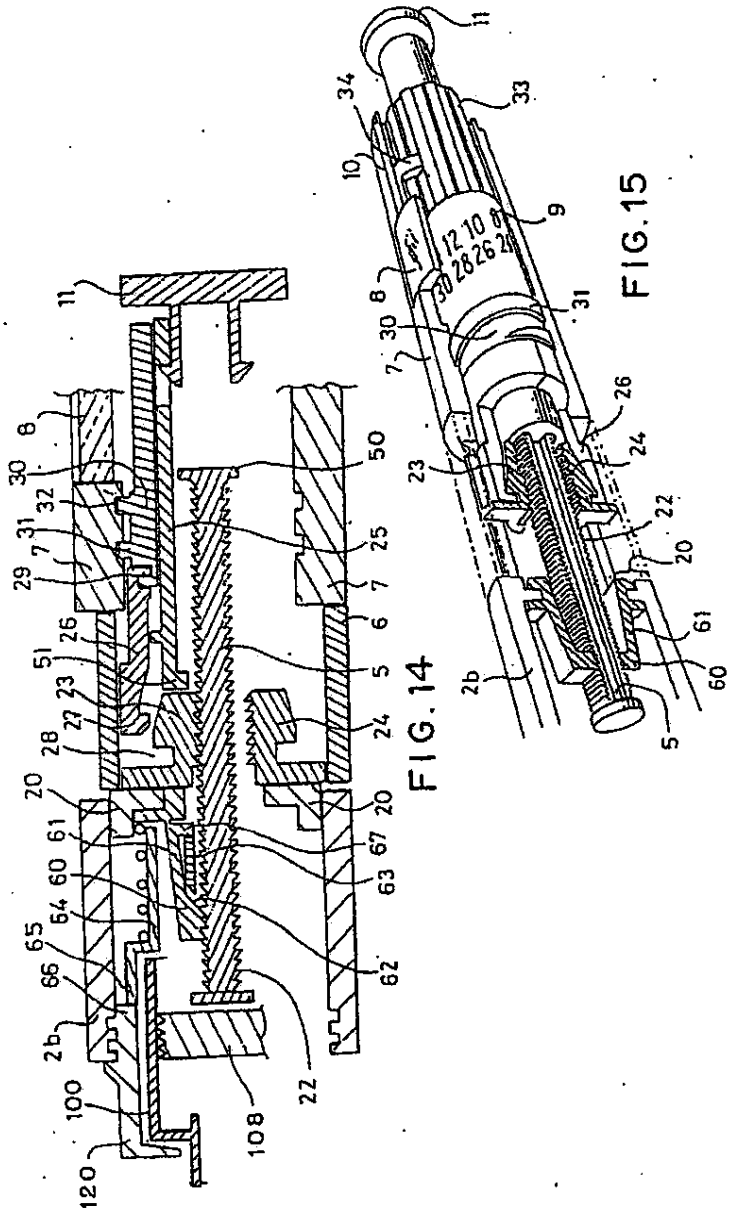


FIG. 14

FIG. 15

CARTRIDGE-HOLDER ASSEMBLY FOR MEDICATION DISPENSING UNIT

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of copending U.S. patent application Ser. No. 07/205,198, filed Jun. 10, 1988, now U.S. Pat. No. 4,865,591, which is in turn a continuation-in-part of U.S. patent application Ser. No. 07/081,241, filed Aug. 4, 1987, now abandoned. The entire text of these applications Ser. Nos. 07/205,198 and 07/081,241 is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

The present invention relates to a cartridgeholder assembly for a measured dose medication dispensing device.

Patients suffering from diabetes often have to inject themselves with frequent doses of insulin and this can be done using a conventional syringe. However, such patients often also suffer from side effects of their illness and are not capable of accurately controlling the operation of such a syringe. It is therefore desirable that they should be provided with means for automatically administering an accurately controlled dosage. The dosage required by different patients can vary over quite wide ranges, from for example 2 units of insulin per dose to 30 or more units, and it is necessary to ensure that any device is capable of selecting a range of dosages simply and accurately.

Dispensing devices such as that shown in Rex U.S. Pat. No. 4,592,745 utilize a cartridge having a pierceable membrane at one end and a movable piston at the other, with a volume of a medication such as an insulin solution contained therebetween. The cartridge is mounted in a dispensing device which includes a plunger, a one-way mechanism that permits the plunger only to advance, and a mechanism for advancing the plunger to dispense medication.

The device disclosed in the Rex patent utilizes the rear rim of the cartridge to actuate the one-way mechanism: when the cartridge is removed the one-way mechanism releases, allowing the plunger to retract, but when the dispensing device is assembled with the cartridge in place the rear rim of the cartridge causes the one-way mechanism to engage the plunger. The cartridge is received loosely in a section of the device, and the one-way mechanism engaging apparatus resiliently holds the cartridge in position.

The dispensing device of the Rex patent has been proven effective and reliable in use. Nonetheless, it suffers from certain disadvantages related to the fact that the walls of the cartridge are formed of glass and in commercially practical cartridges it is difficult to control the overall length of the cartridge accurately. Resulting variations in the length of the cartridge cause the one-way mechanism to be engaged at a variable position as the cartridge enclosing section is screwed into place in the dispensing unit. If the cartridge is unusually long, the one-way mechanism will be engaged well before the cartridge enclosing section reaches its final position, and the plunger will then pressurize the contents of the cartridge as the section is screwed home. Such pressurization will produce a squirt of medication when the needle pierces the membrane. Some users may object to this unintended release of medication.

The variable length of the cartridge also imposes design constraints on the Rex dispensing device. As mentioned above, the cartridge fits loosely within the cartridge receiving section, and the cartridge is held in position by forces applied to the rear rim of the cartridge by the engaging apparatus for the one-way mechanism discussed above. This engaging apparatus must provide resilient support to the rim over the full range of cartridge lengths. Otherwise, the cartridge may be subjected to excessive axial forces, or it may alternately be left free to move axially in the dispensing device. The resilient mounting of the engaging apparatus in no way overcomes the problems discussed above related to unintended pressurization of the cartridge.

The present invention is directed to an improved cartridge-holder assembly that overcomes these prior art problems.

SUMMARY OF THE INVENTION

According to this invention, a cartridgeholder assembly is provided for a syringe-type medication dispensing unit. The cartridge comprises a cartridge body having first and second ends, a pierceable membrane mounted at the first end, and a piston mounted at the second end, with a volume of medication contained in the cartridge body between the membrane and the piston. The holder defines a first holder end which defines a central opening and means for mounting a double ended needle. The second holder end defines means for securing the holder to a medication dispensing unit and an actuating shoulder. The holder defines a central cavity shaped to receive and frictionally engage the cartridge to form an assembly that can be handled as a single, modular unit with the cartridge held frictionally in the holder.

This arrangement overcomes the prior art problems discussed above. The holder can easily be manufactured to high precision, and the actuating shoulder can therefore be accurately positioned to actuate the one-way mechanism just as the holder reaches its fully assembled position on the dispensing device. This substantially eliminates the problem of unintended pressurization of the cartridge before the needle is inserted into the membrane. Secondly, the releasable engagement between the cartridge and the holder allows the cartridge to be held in place without engagement of the rim. This relaxes design constraints on the engaging apparatus for the one-way mechanism.

As yet another advantage, the modular assembly of the holder and cartridge can be handled and assembled onto the dispensing device as a unit. This simplifies assembly by the patient.

The housing is preferably formed from a clear plastic material, and a user can therefore readily observe the movement of the piston within the cartridge and can assess the amount of medication in the cartridge. The housing also provides a measure of protection to the cartridge, both physical and against pathogenic organisms and other possible contamination.

The needle end of the cartridge can project through a terminal aperture in the housing or that end of the housing can be closed and can carry a needle or other outlet integrally therewith which projects axially inwardly into the housing to penetrate the membrane at the end of the cartridge.

The cartridge houses the piston which is to be moved by the plunger of the dispensing device. This piston can

be of conventional design and will usually form part of the cartridge as commercially available. The plunger acts on the piston and the piston can carry a socket or other recess to receive and locate the head of the plunger. In some cases, the plunger can be affixed to the piston and will form part of the cartridge as supplied, in which case the plunger will extend into the device when the cartridge is mounted on the device. However, it is preferred that the plunger form part of the device rather than of the cartridge and, for convenience the invention will hereinafter be described with respect to this configuration.

The invention itself, together with further objects and attendant advantages, will best be understood by reference to the following detailed description, taken in conjunction with the accompanying drawings

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a syringe-type medication dispensing unit which includes a preferred embodiment of the cartridge-holder assembly of this invention.

FIG. 2 is a partial view of portions of the unit of FIG. 1 in partial section.

FIG. 3 is an exploded perspective view of the cartridge-holder assembly of FIG. 1.

FIG. 4 is a front view in partial cutaway of the holder of FIG. 3.

FIG. 5 is a cross sectional view taken along line 5—5 of FIG. 3.

FIG. 6 is a cross sectional view taken along line 6—6 of FIG. 3.

FIG. 7 is a rear view of the holder of FIG. 3.

FIG. 8 is a longitudinal sectional view taken along line 8—8 of FIG. 7 in partial elevation.

FIG. 9 is an exploded perspective view of portions of the dispensing device of FIG. 1.

FIG. 10 is a sectional view taken along line 10—10 of FIG. 9.

FIG. 11 is an elevational view in partial cutaway of the cap of FIG. 1.

FIG. 12 is a cross sectional view taken along line 12—12 of FIG. 11.

FIG. 13 is a cross sectional view taken along line 13—13 of FIG. 11.

FIG. 14 is a schematic cross sectional view of portions of the dispensing device of FIG. 1.

FIG. 15 is a perspective view in partial cutaway of portions of the dispensing device of FIG. 1.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

FIGS. 1–10 show various views of the preferred embodiment of the cartridge-holder assembly of this invention, and FIGS. 11–15 provide further details relating to a preferred dispensing unit suitable for use with the cartridge-holder assembly of FIGS. 1–10.

Turning now to FIGS. 1–10, the preferred embodiment of the assembly of this invention comprises a cartridge 100 and a cartridge holder 120. FIG. 1 shows the holder 120 mounted to a dispensing device, and FIG. 2 shows the cartridge 100 mounted within the holder 120. As best shown in FIGS. 2 and 3, the cartridge 100 includes a generally cylindrical body 102 which is closed at one end by a pierceable membrane 104 and is sealed at the other end by a movable piston 108. A medication such as an insulin solution 110 is contained within the body 102 between the membrane 104 and the piston 108. In the conventional manner, a collar 106 of metal surrounds the membrane 104 and secures the membrane 104 to the body 102 in a fluid-tight manner.

The cartridge 100 can be quite similar to conventional glass cartridges. Of course, the dimensions of the cartridge should be chosen to match the dispensing device. Preferably, the body 102 is glass coated with silicone to reduce friction with the piston. The piston 108 is preferably about two-thirds the axial length of conventional pistons, also to reduce friction.

As best shown in FIGS. 2 and 8, the cartridge holder 120 comprises a tubular element 122 which defines a narrowed neck 124 which terminates in a central opening 125. External threads 126 are formed around the exterior of the neck 124. The opposite end of the cartridge holder 120 defines an annular actuating shoulder 128 positioned adjacent to a second set of external threads 130. The tubular element 122 is sized to receive the cartridge 100 and defines in this embodiment two axially oriented raised lands 132 which are positioned to frictionally engage the collar 106 of the cartridge 100.

The exterior of the tubular element 122 defines a number of features which cooperate with other components of the dispensing device described below. In particular, the tubular element 122 defines a pair of axial grooves 134 which communicate with respective circumferential grooves 136 to form L-shaped grooves that form part of a bayonet mount as described below. The tubular element 122 also defines a pair of stop members 138 which cooperate with a cap as described below. Each of the stop members 138 defines a transverse face 140 and an opposed sloping face 142. The tubular element 122 also defines an annular flange 143 which in turn defines two rearwardly extending stop members 144. A pair of ramps 146 are defined on the exterior of the tubular member 122 near the external threads 130.

Preferably, the cartridge holder 120 is formed of a transparent plastic material such as polycarbonate. This construction allows a user to see the cartridge 100 within the cartridge holder 120 to check the correct insulin and to gauge the amount of medication 110 left in the cartridge 100.

The minimum diameter of the inside of the tubular element 122 is greater than the maximum diameter of the cartridge 100. For this reason, the tubular element 122 receives the cartridge 100 in an easy sliding fit such that the weight of the cartridge 100 will move the cartridge 100 in the tube 122 until the collar 106 contacts the raised lands 132. A slight additional force will push the cartridge 100 to the fully seated position shown in FIG. 8. In this position friction between the lands 132 and the collar 106 will prevent the cartridge 100 from falling out of the holder 120. This arrangement facilitates assembly of the cartridge 100 into the holder 120, because no frictional retarding force is encountered until the cartridge 100 is almost in the fully assembled position. There is therefore, less chance that a user will fail to push the cartridge 100 fully into the holder 120. Furthermore because the cartridge 100 is engaged at the collar 106, it is the diameter of the collar 106 rather than the diameter of the tube 122 that determines the tightness of the friction fit. In many cases, the diameter of the collar 106 can be controlled more closely than the diameter of the glass tube 122, and in these cases this arrangement provides the further advantage of a more consistent fit.

Thus, the lands 132 frictionally engage the collar 106 to releasably hold the cartridge 100 in the holder 120

and thereby to form a modular unit which can be handled and assembled as a single device. As apparent in FIGS. 2 and 8, the end of the cartridge 100 that mounts the piston 108 extends out of the cartridge holder 120 for a considerable distance. In this embodiment, that distance is greater than one-half inch. This allows the user to grasp the cartridge 100 when it is necessary to remove the cartridge 100 from the cartridge holder 120 for replacement.

As shown in FIG. 2, the external threads 126 are sized to mate with internal threads 156 defined by a needle assembly 150. This needle assembly 150 includes a double-ended hypodermic needle 152 which is mounted to a hub 154 that in turn defines the internal threads 156. By threading the needle assembly 150 onto the external threads 126 the needle 152 is passed through the central opening 125 and the membrane 104, into contact with the medication 110.

As shown in FIGS. 1 and 11-13 the dispensing device includes a removable cap 160 which, when mounted in position, surrounds and protects the needle assembly 150 (if mounted), the cartridge holder 120, and the cartridge 100. This cap 160 defines a pair of internal lugs 162 sized to fit within the grooves 134, 136 to form a bayonet mount in order to hold the cap 160 securely in position on the cartridge holder 120. In addition, the cap 160 defines a pair of protruding elements 164 positioned to interact with the stop members 138. When the cap 160 is rotated in a first locking direction, the protruding elements 164 engage the transverse faces 140, thereby defining a stop position. This allows the cap 160 to be used as a tool to apply torque to screw the cartridge holder 120 into place on the dispensing device without overtightening the bayonet mount. When the cap 160 is rotated in a second unlocking direction, the protruding elements engage the sloping faces 140 to shift the cap 160 axially. The cap 160 can if desired define a clip 166 to retain the dispensing device in a pocket of the user.

As shown in FIGS. 2 and 9 the cartridge holder 120 mounts in the dispensing device by screwing the external threads 130 into a collar 2b defined by the dispensing device. This collar 2b defines internal threads 176 which mate with the external threads 130. In addition the collar 2b defines elements which cooperate with the stop members 144 and the ramps 146 to define the fully assembled position of the cartridge holder 120 and to hold it in that position. In particular, the collar 2b defines a pair of spiral grooves 170, each of which terminates in a transverse face 172. When the cartridge holder 120 is threaded into the collar 2b the stop members 144 enter the spiral grooves 170. The faces 172 prevent overtightening of the cartridge holder 120 in the collar 2b. The collar 2b defines ramps 174 which cooperate with the ramps 146 to define a detent that tends to hold the cartridge holder 120 in the fully assembled position (FIG. 10).

As best shown in FIG. 2, when the cartridge holder 120 is assembled in the collar 2b the rear end of the cartridge 100 is unrestrained. This arrangement provides particular advantages, because the overall length of the cartridge 100 is difficult to control with conventional manufacturing processes, as explained above. This embodiment accommodates varying lengths of the cartridge 100 because the rear rim of the cartridge body 102 does not contact the dispensing unit. In order to prevent the cartridge 100 from moving undesirably after the cartridge holder 120 has been threaded into the collar 2b, the cartridge 100 is restrained from movement by the frictional fit with the raised lands 132 described above.

As described in greater detail below, the dispensing device includes a plunger 5 that is advanced against the piston 108 to dispense the medication 110 through the needle 152.

The movement of this plunger 5 is controlled in part by a one-way mechanism that allows the plunger 5 to advance but not to retract as long as the cartridge holder 120 is mounted to the collar 2b. However, when the cartridge holder 120 is removed from the collar 2b to replace the cartridge 100, this one-way mechanism is released, to allow the plunger 5 to be retracted into the dispensing unit. The details of operation of this one-way mechanism and the manner in which this mechanism is released are explained in detail below in conjunction with FIGS. 14 and 15. Here, it is enough to note that the one-way mechanism is controlled by the axial position of a member 64 which is slidably mounted in the collar 2b. This member 64 abuts the actuating shoulder 128 of the cartridge holder 120 and is shifted rearwardly to engage the one-way mechanism with the plunger 5 when the cartridge holder 120 is mounted in place in the collar 2b.

It is the actuating shoulder 128 rather than any part of the cartridge 100 that determines the position of the one-way mechanism actuating member 64. The cartridge holder 120 can readily be manufactured to high accuracy with conventional molding techniques, and for this reason the actuating shoulder 128 can be precisely positioned to ensure that the member 64 is depressed at the proper instant, just before the cartridge holder 120 is fully assembled into the collar 2b. This ensures that there is no substantial movement of the cartridge holder 120 or the cartridge 100 after the one-way mechanism is engaged. This prevents the plunger 5 from exerting undue forces on the piston 108 and minimizes the unintended discharge of medication 110 when the needle 152 pierces the membrane 104.

Further details of the one-way mechanism, and the operation of the actuating member 64, as well as the advancing mechanism for the plunger 5 will now be described in conjunction with FIGS. 14 and 15.

As shown in highly schematic form in FIG. 14 and as discussed above, the cartridge 100 is housed in the housing 120 which is screw fit into the collar 2b extending axially from the front end of the dispensing unit.

The dispensing device is provided with a pawl type one-way mechanism which engages teeth on the plunger 5 so as to prevent rearward movement of the plunger 5 once the housing 120 is in place. This one-way mechanism is shown at 60 in FIGS. 14 and 15 and is biassed to retract radially when the cartridge housing 120 is removed. For example, the housing can incorporate a twist mechanism which both locks the cartridge housing in position and actuates the one-way mechanism; or the shoulder 128 of the cartridge housing 120 can bear against part of the one-way mechanism as it seats home to actuate the one-way mechanism. The one-way mechanism disengages when the cartridge housing 120 is removed to allow the plunger 5 to be retracted into the device to permit a new cartridge 100 to be mounted on the dispensing device.

A preferred form of the one-way mechanism is shown in FIG. 14 and comprises a pair of diametrically opposed pawls 60 carried on spring arms 61 snap fitted onto an annular shoulder 20 to extend forward of the

shoulder into the axial socket in which the cartridge 100 is received. The pawls 60 have an inclined rearward face 62 which bears against a correspondingly angled face carried by a collet 63 mounted around the plunger shank and radially inward of arms 61. The collet is attached to a spring loaded sleeve 64 which is a slideable fit within the socket and is spring biassed into its forward position. The front end of the sleeve 64 provides a stop 65 against which the shoulder 128 of the housing 120 bears as it is mounted in the device. This causes the sleeve 64 to be moved axially rearwardly to carry the inclined face of collet 63 clear of the inclined face 62 of the pawl and to bring the rear edge of collet 63 into contact with a stop 67 carried on the radially inward face of arm 61. This causes the arm 61 to flex radially inward and urge pawl 60 into engagement with the teeth on the plunger 5. When the housing 120 is removed to fit a new cartridge 100, this allows the sleeve 64 to move forward under the thrust of the spring so that collet 63 moves forward of release stop 67 and bears against the inclined face 62 to lift the pawl 60 clear of the teeth on the plunger 5. The plunger 5 can now be retracted into the device to enable another cartridge 100 to be fitted. By using the rear of the accurately molded housing 120 to actuate the pawl mechanism 60–67, rather than the rim of the cartridge 100, variations in the size of the cartridge 100 can be accommodated.

Rearwardly of shoulder 20, the body of the device houses the plunger drive mechanism, the means for engaging and disengaging the drive mechanism from the plunger, and the dosage selection means. In the form of the device shown, these take the form of a series of members concentrically journalled around the plunger 5.

As shown the housing comprises a rotatable section 6 which houses the drive engagement mechanism; a fixed section 7 containing the dosage selection mechanism and having a port 8 through which a scale 9 indicating the dose selected can be seen by the user; a further rotatable collar or sleeve 10 for operating the dosage selection mechanism: and a terminal axially operating push button 11 for driving the plunger 5 forward to dispense the selected dose. The various sections of the housing can have any desired external shape, but it is preferred that the housing 1, sleeve 6 and section 7 have an oval external cross-section so that the relative rotational position of one with respect to the other can readily be detected by a user, notably by a blind person.

The plunger 5 preferably has a substantially circular cross-section but can have a squared, triangular or other cross-section shape if desired. For example, as shown in FIG. 15, it may have two opposed flats along its length to guide the drive means.

The plunger 5 carries a series of circumferential ribs or teeth 22 which form an axial ratchet into which the one-way mechanism 21 and the radially clampable drive mechanism described below engage. The teeth 22 are of a saw tooth form with a scarp face of the teeth directed rearwardly. Preferably, the teeth extend axially for the full length of the plunger 5. It is preferred that the axial distance from one tooth to the next corresponds to a dosage unit for the material being dispensed.

Located to the rear of shoulder 20 is the drive mechanism and the mechanism for engaging and disengaging this from the plunger. The drive mechanism is a pawl type mechanism which is radially engageable and disengageable with the teeth on the plunger and comprises two jaws 23 and 24 diametrically opposed to one another and carrying on their radially inward faces teeth which correspond to and engage with the teeth 22 on the plunger.

The jaws are normally urged radially outwardly, as shown for jaw 24 in FIG. 14, by transverse coil springs acting between the jaws 23 and 24 or by other bias means (not shown) so that their teeth do not engage those of the plunger which is then free to move axially with respect to the jaws when they are in their outward position, but is locked to the jaws when they are in their radially inward position, as shown for jaw 23 in FIG. 14.

The jaws are moved radially inward against the thrust of the coil springs by a pair of cams carried on the internal face of the rotatable section 6 of the housing or formed by the narrower diameter sectors of the oval cross-section of the rotatable section 6. The user has to twist section 6 to engage or disengage the jaws from plunger 5 and thus engage or disengage the drive to the plunger. If desired, section 6 can be spring biassed towards the drive disengaging position so that the user always has to twist section 6 before the device can be used.

The shoulder 20, as shown in FIG. 14, defines the forward limit of the travel of the drive mechanism and provides the datum point from which the dosage is determined. In the device shown in FIGS. 14 and 15 the forward faces of jaws 23 and 24 butt against the rear face of shoulder 20 to set the zero or datum point for the dosage selection mechanism.

A push sleeve 25 journalled on plunger 5 and within the dosage selection mechanism described below acts axially on the rear faces of the jaws 23 and 24 when in their drive engaged position to drive the jaws and hence the plunger 5 forward. When the jaws are in the drive disengaged position, they still bear against the push sleeve so that they carry it axially rearwards with them during the dosage selection. The push sleeve 25 provides the mechanical link between the terminal push button 11 which a user presses and the jaws 23 and 24.

The jaws 23 and 24 are moved axially by means of a split jaw drive sleeve 26 which has forward hooks 27 which engage similar recesses 28 at the rear of the jaws and rearward hooks 29 or other flexible linkages which connect the sleeve 26 axially to the forward end of the screw sleeve 30 of the dosage selection mechanism. When the jaws are in the drive disengaged position as shown for jaw 24 in FIG. 14 the hooks 27 and recesses 28 are engaged and the jaws can be moved axially with the screw sleeve 30. When the jaws are in the drive engaged position, as shown for jaw 23 in FIG. 14, the hooks 27 are released from recesses 28 to permit the jaws to move axially with sleeve 25 and free from the screw sleeve 30.

The dosage selection mechanism is housed within section 7 of the housing and comprises a screw sleeve 30 journalled for rotation and axial movement upon push sleeve 25. Sleeve 30 carries an external screw thread 31 which engages a similar thread 32 carried internally by section 7 of the body of the device. Sleeve 30 is rotated and thus caused to move axially by means of a collar driving the sleeve through a spined drive 33 shown in FIG. 15. The window insert in port 8 preferably has a ratchet or clicker mechanism 34 to give an audible indication as the dose is selected.

Retraction of sleeve 30 carries the jaw drive sleeve 26 and the jaws 23 and 24 with it when they are in the

disengaged position and the dose selected can be seen through port 8. Re-engagement of jaws 23 and 24 with the plunger breaks the latch 27/28 and allows the push sleeve 25 and the jaws 23 and 24 to move independently of the screw sleeve 30 and the jaw drive sleeve 26.

To indicate when there is insufficient fluid left in the cartridge to achieve the next dose, a radial shoulder or stop 50 is located at or adjacent the rearward end of plunger 5. This co-operates with a corresponding stop or shoulder 51 at the forward end of the push sleeve 25. The stops engage when the push sleeve is retracted to the maximum extent possible as the plunger 5 approaches the extreme of its forward travel. The user can then see from the dose displayed at the port 8 whether the cartridge contains the requisite amount of fluid. Since the plunger drive is not engaged at this time, the user can then set the dosage mechanism to the required dose if this is less than the amount indicated as remaining in the cartridge without having to discharge fluid as with a conventional device.

Push sleeve 25 is provided with a push button end cap 11 protruding axially from the body of the device which the user depresses to drive the sleeve 25 forward within the housing until the front face of jaws 23 and 24 butt against the rear of shoulder 20. The jaws 23 and 24 can only be moved rearwardly when they have been disengaged from the teeth 22 on the plunger 5, since the one-way mechanism will prevent rearward movement of the plunger 5. If a user attempts to set the dosage mechanism while the drive is engaged, he will detect resistance to rotation of sleeve 10. If he ignores this, the spline drive 33 between collar 10 and the screw sleeve 30 will be over-ridden to release the screw sleeve to prevent damage to the mechanism. However, unless the drive is engaged, depression of button 11 will not achieve any forward movement of the jaws or discharge of fluid from the cartridge 100.

The above device can be manufactured in many suitable materials and readily lends itself to manufacture by injection molding of suitable plastics materials with the various components being snap fits upon one another.

In operation, a user initially prepares the dispensing device for use by removing the holder 120, inserting a cartridge 100 in the holder 120, and then screwing the holder 120 into place on the collar 2b. The needle assembly 150 is then screwed into place on the housing 120. The user then rotates the sleeve 6 to disengage the drive mechanism if this has not already been done. Jaws 23 and 24 should be seated against the rear face of shoulder 20, the zero setting, from the previous use of the device, but the screw sleeve 30 will be at the dosage position previously selected. The user can thus see what dose was last administered where a sequence of different doses has to be administered. Collar 10 is rotated, say clockwise, to bring sleeve 30 to its forward position at which the latching mechanism 27/28 engages the jaws 23 and 24 and seats them firmly against the rear face of stop 20. The engagement of the latches can be used to provide an audible signal when this occurs, or the resistance to further forward movement will provide the signal to the user that the zero setting has been reached. The dosage displayed through port 8 will now read zero.

Collar 10 is then rotated counter-clockwise the desired number of turns, as evidenced by the number of clicks heard or by the dose displayed at the port 8, to retract screw sleeve 30, the jaw drive sleeve 26 and the jaws 23 and 24 and the push sleeve 25 the desired distance with respect to plunger 5. This will also cause the push button 11 to be extended from the rear end of the device. If the user inadvertently turns the collar 10 too far, it can be rotated clockwise to the correct position without moving the plunger.

Sleeve 6 is then rotated to re-engage the positive drive between the push sleeve 25, the jaws 23 and 24 and the plunger 5. This action will also disengage the latch 27/28 between jaws 23 and 24 and the jaw drive sleeve 26. At this point the device is cocked and ready to dispense the desired dose from the cartridge. However, the device has required a series of positive actions to achieve this state and would not normally be retained by a user in the cocked state, but would be stored with the drive disengaged so that accidental actuation of the device can not occur.

The user then inserts the point of needle 3 into his arm, buttock or other suitable point in his body and depresses button 11 to administer the dose of insulin. The dose is administered by depressing the button fully. If the button is not depressed fully, the user can detect this and can complete the dose administration. If desired, a colored band can be mounted around button 11 which will remain partially exposed until the button is fully depressed. Release of pressure on button 11 does not allow the plunger 5 to retract as with previous designs, so that jerky or interrupted depression of button 11 does not allow the user to pump the device to administer an excessive dose.

When the full dose has been administered, the jaws 23 and 24 will butt against the rear of shoulder 20. Due to the action of the one-way mechanism 21, 60-67, the blocks 23 and 24 cannot be retracted and administration of a further dose of insulin is not possible until the whole process of dose selection and re-cocking of the device is carried out. The device will therefore resist accidental overdosing due to repeated pressing of button 11.

As stated above, the cartridge-holder assembly of this invention finds use wherever it is desired to provide a removable cartridge for a measured dose syringe, for example in the administration of other medicaments or in dispensing accurately known amounts of a fluid, for example in blood tests or analytical work. It will also be appreciated that the assembly may be altered in ways which do not affect the fundamental operating concept of the assembly, for example by using other materials and configurations.

It is therefore intended that the foregoing detailed description be regarded as illustrative rather than limiting, and that it be understood that it is the following claims, including all equivalents, which are intended to define the scope of this invention.

I claim:

1. A cartridge assembly for a syringe-type medication dispensing unit, said assembly comprising:

a cartridge comprising a cartridge body having first and second ends, a pierceable membrane mounted at the first end, and a piston mounted at the second end, with a volume of mediation contained in the cartridge body between the membrane and the piston;

a cartridge holder having first and second ends, said first holder end defining a central opening and means for mounting a double ended needle, said second holder end defining means for securing the holder to a medication dispensing unit and an actuating shoulder, said holder defining a central cavity;

one of said central cavity and said cartridge being shaped with a plurality of raised lands adapted to frictionally to engage the opposed surface of the other of said cartridge and cavity so as to form an assembly which can be handled as a single modular unit with the cartridge held securely in the holder.

2. The invention of claim 1 wherein the double ended needle mounting means comprises a first set of external threads.

3. The invention of claim 1 wherein the holder securing means comprises a second set of external threads.

4. A cartridge assembly for a syringe-type medication dispensing unit, said assembly comprising:

a cartridge comprising a cartridge body having first and second ends, a pierceable membrane mounted at the first end, and a piston mounted at the second end, with a volume of medication contained in the cartridge body between the membrane and the piston;

a cartridge holder having first and second ends, said first holder end defining a central opening and means for mounting a double ended needle, said second holder end defining means for securing the holder to a medication dispensing unit and an actuating shoulder, said holder defining a central cavity shaped to receive and frictionally engage the cartridge to form an assembly which can be handled as a single, modular unit with the cartridge held securely in the holder;

wherein the holder securing means comprises a second set of external threads; and

wherein the modular unit is mounted to a syringe type medication dispensing unit having a plunger engageable with the piston, a one-way mechanism engaged with the plunger, and an actuating member for the one-way mechanism, wherein the second holder end is received within the dispensing unit, wherein the second set of external threads is engaged with the dispensing unit, and wherein the actuating shoulder is engaged with the actuating member.

5. The invention of claim 4 wherein the dispensing unit and the holder define a detent system which holds the second set of external threads in engagement with the dispensing unit.

6. The invention of claim 5 wherein the detent system comprises inter engaging ramps on the holder and the dispensing device adjacent the second set of external threads.

7. The invention of claim 1 wherein the modular unit is mounted to a cap which encloses the first end of the holder, wherein the holder defines at least one stop member wherein the cap defines at least one lug, wherein at least one of the stop member and lug has a transverse face and a sloping face oriented such that the stop member and lug abut at the transverse face to limit rotation of the cap when the cap is rotated in a first direction with respect to the holder, and the stop member and the lug abut at the sloping face to shift the cap axially along the holder when the cap is rotated in a second direction with respect to the holder.

8. The invention of claim 1 wherein the modular unit is mounted to a cap which encloses the first end of the holder; wherein one of the holder and the cap defines at least one groove having an axial portion and a circumferential portion; and wherein the other of the holder and the cap defines a protruding element shaped to slide in the groove to secure the cap and holder together in a bayonet mount.

9. The invention of claim 1 wherein the holder frictionally engages only the first end of the cartridge.

10. The invention of claim 9 wherein the cartridge defines an annular collar disposed around the membrane, and wherein the holder frictionally engages the cartridge only at the collar.

11. The invention of claim 10 wherein the plurality of raised lands are positioned on the holder to frictionally engage the collar.

12. The invention of claim 2 further comprising:

a needle assembly comprising a double ended needle secured to a mounting element which defines a set of internal threads engaged with the first set of external threads of the holder, with one end of the needle passing through the membrane and in contact with the medication.

13. The invention of claim 1 wherein the medication comprises an insulin solution.

14. The invention of claim 1 wherein the second end of the cartridge extends out of the holder by a distance of about ¼ inch or more.

15. A cartridge assembly for a syringe-type medication dispensing unit, said assembly comprising:

a cartridge comprising a cartridge body having first and second ends, a pierceable membrane mounted at the first end, and a piston mounted at the second end, with a volume of medication contained in the cartridge body between the membrane and the piston and an annular collar disposed around the membrane;

a cartridge holder having first and second ends, said first holder end defining a central opening and a first set of external threads, said second holder end defining an actuating shoulder and a second set of external threads said holder defining a central cavity shaped to receive the cartridge with the pierceable membrane adjacent the central opening, said cartridge having a length greater than that of the holder such that the second end of the cartridge extends out of the holder,

said holder defining a plurality of raised lands positioned to frictionally engage the collar to form an assembly which can be handled as a single, modular unit with the cartridge held removably in the holder by friction between the collar and the holder, said holder shaped to receive the cartridge freely until the lands engage the collar, such that the weight of the cartridge will move the cartridge into the holder until the lands contact the collar.

16. The invention of claim 15 wherein the modular unit is mounted to a syringe type medication dispensing unit having a plunger engageable with the piston, a one-way mechanism engaged with the plunger, and a one-way mechanism actuating member, wherein the second hold end is received within the dispensing unit, wherein the second set of external threads is engaged with the dispensing unit, and wherein the actuating shoulder is engaged with the one-way mechanism actuating member.

17. The invention of claim 16 wherein the dispensing unit and the holder define a detent system which the second set of external threads in engagement with the dispensing unit.

18. The invention of claim 17 wherein the detent system comprises inter-engaging ramps on the holder

and the dispensing device adjacent the second set of external threads.

19. The invention of claim 18 wherein the modular unit is mounted to a cap which encloses the first end of the holder, wherein the holder defines at least one stop member, wherein the cap defines at least one lug, wherein at least one of the stop member and lug has a transverse face and a sloping face oriented such that the stop member and lug abut at the transverse face to limit rotation of the cap when the cap is rotated in a first direction with respect to the holder, and the stop member and the lug abut at the sloping face to shift the cap axially along the holder when the cap is rotated in a second direction with respect to the holder.

20. The invention of claim 15 wherein the modular unit is mounted to a cap which encloses the first end of the holder; wherein one of the holder and the cap defines at least one groove having an axial portion and a circumferential portion; and wherein the other of the holder and the cap defines a protruding element shaped to slide in the groove to secure the cap and holder together in a bayonet mount.

21. The invention of claim 15 further comprising:

a needle assembly comprising a double ended needle secured to amounting element which defines a set of internal threads engaged with the first set of external threades of the holder, with one end of the needle passing through the membrane and in contact with the medication.

22. The invention of claim 15 wherein the medication comprises insulin.

23. The invention of claim 15 wherein the lands are axially oriented.

* * * * *

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United States Patent [19]

Harris

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[54] MULTIPLE DOSE INJECTION PEN

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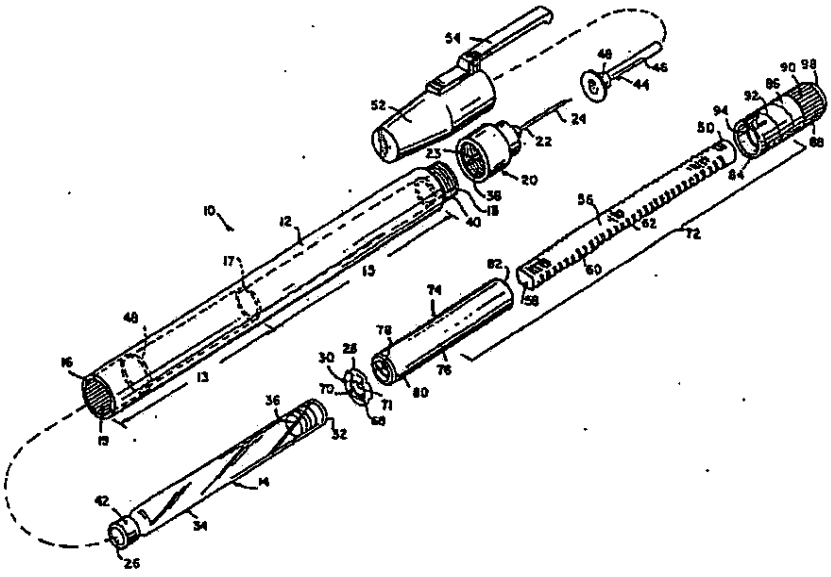
Primary Examiner—Michael H. Thaler
Assistant Examiner—C. Maglione
Attorney, Agent, or Firm—Douglas J. Taylor; Leroy Whitaker

[57] ABSTRACT

The present invention relates to a hypodermic syringe having the same general appearance as a pen which is specifically adapted to provide for multiple measured injections of materials such as insulin or human growth hormone.

17 Claims, 3 Drawing Sheets



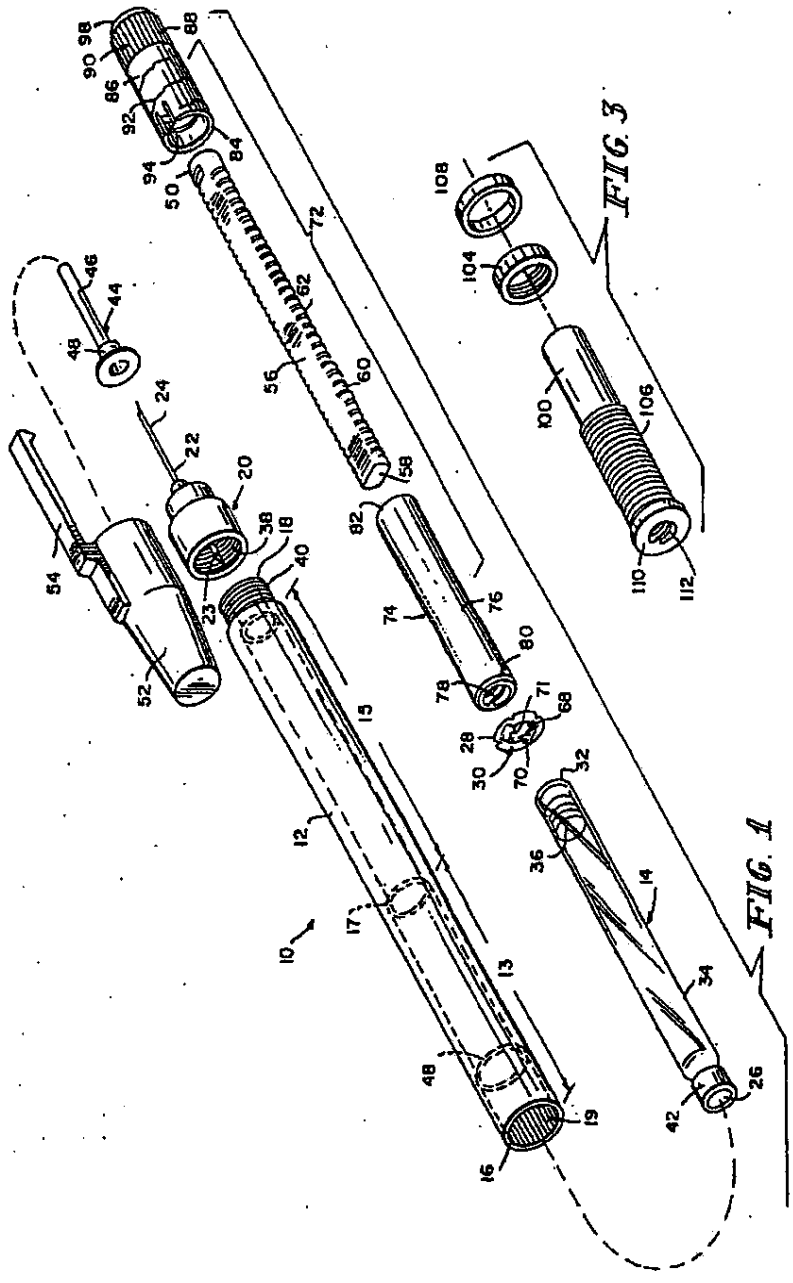

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FIG. 3

FIG. 1

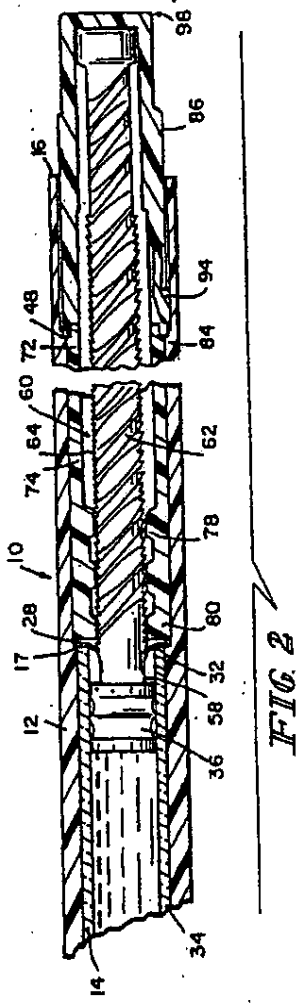
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FIG. 2

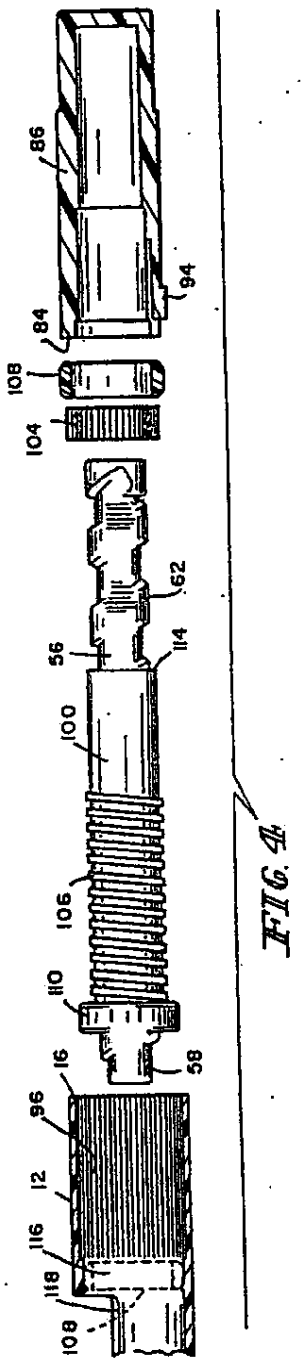
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FIG. 4

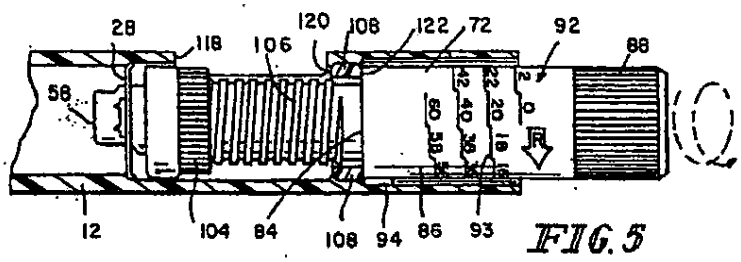

FIG. 5

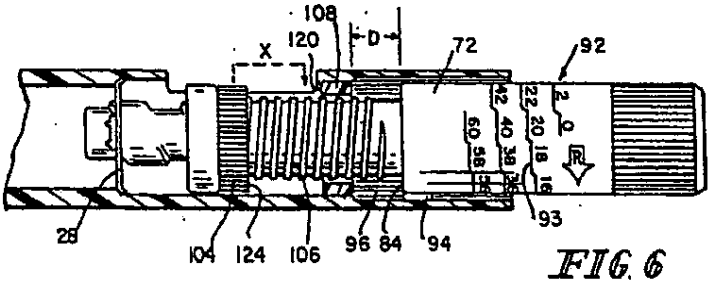

FIG. 6

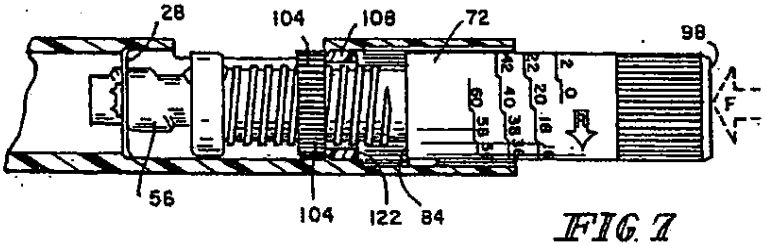

FIG. 7

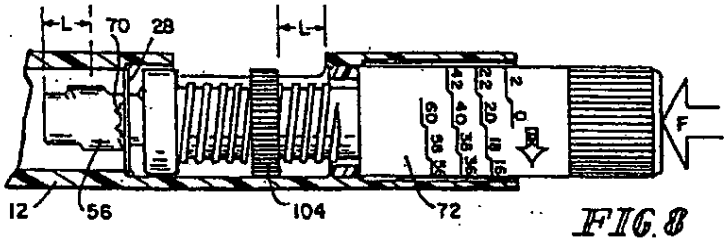

FIG. 8

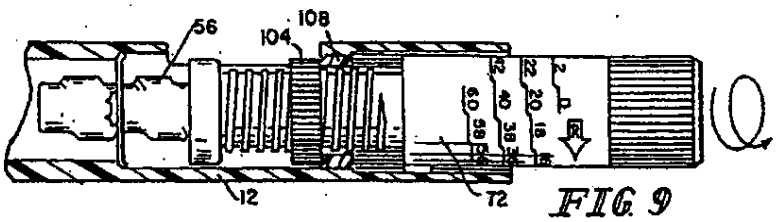

FIG. 9

MULTIPLE DOSE INJECTION PEN

The present application is a continuation application of copending application Ser. No. 07/361,132, filed Jun. 5, 1989, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates generally to devices suitable for use in dispensing a measured amount of liquid material from a container. The invention particularly relates to a hypodermic syringe having the same general appearance as a pen which is specifically adapted to provide for multiple measured injections of materials such as insulin or human growth hormone.

Diabetics and others frequently find themselves in situations where the assistance of a health professional to administer the subcutaneous or intramuscular injection of measured amount of a liquid agent is generally not available. In such situations such persons need to have a low cost syringe which does not require the assistance of a health professional to achieve the desired measure of accuracy. It is often the case that such persons require more than one dose per day, each dose being of a somewhat different volume. Dispensers of this general type are known which have the general appearance of a pen or mechanical pencil. The dispenser is typically large enough to hold several such doses, yet it is small enough to fit conveniently in one's pocket or purse. Examples of such devices are to be found in U.S. Pat. Nos. 4,413,760; 4,498,904; and 4,592,745. Additional examples are shown in PCT International Publications WO 87/02895 and WO 88/07874.

In devices of this class, a container of the liquid is provided having a closed first end adapted to be penetrated by a needle assembly so as to permit the liquid in the container to pass out the closed first end for subcutaneous or intramuscular injection. The second end of the container is generally closed by a piston. To prevent tampering or reuse of the liquid container, the piston is generally designed such that a pushing force can be applied to the piston to reduce the liquid-holding volume of the container, but no feature is presented which would be suitable for pulling on the piston so as to enlarge the liquid-holding volume of the container.

An elongated member in the nature of a plunger rod is received within the housing for exerting a force on the piston closing the second end of the container. A means is provided for measuring the distance which the plunger rod travels to determine the decrease in volume of the liquid container which causes the dispensing of the liquid within the container. It has generally been recognized that the dispenser should have some feature which would allow the rod to only travel in a single direction toward the piston thereby preventing any action on the part of the rod which might permit an enhancement of the volume of the liquid container. A safety cover is generally provided over a needle assembly attached to the closed end of the container.

While the prior art pen-style syringes have met with some success, certain shortcomings have also been observed. In some prior art pens, the adjustment of the dose to be injected, once made, cannot be accurately diminished to a smaller value. This results in an unnecessary waste of the medicating liquid within the syringe. In some prior art pens, the indication of dose is difficult to read. Prior art pens have sometimes required the patient to read two scales and/or to do some computations in order to determine the dosage delivered. Further, most prior art devices are specifically intended for repeated use generally by substitution of containers within the syringe which can contribute to the unethical use of the syringe in connection with non-prescribed substances.

SUMMARY OF THE INVENTION

In order to overcome these and other shortcomings of the prior art, a syringe constructed in accordance with the present invention includes a housing for holding a container of liquid similar to that known in the prior art. A plunger rod is received within the housing for exerting a force on a piston closing a second end of the container. The plunger rod has a non-cylindrical cross-section with a first surface including threads and a second surface which can, optionally, include a line of ratchet teeth. A collar is received within the housing adjacent to the container second end for permanently retaining the container of liquid within the housing. The collar has a non-cylindrical opening corresponding generally to the cross-section of the plunger rod. The plunger rod passes through the non-cylindrical opening and is prevented from rotating with respect to the housing by the collar. A means on the collar engages the second surface of the plunger rod for restricting movement of the plunger rod away from the container of liquid.

A hollow cap envelops the plunger rod end opposite the container of liquid. A skirt of the hollow cap extends inside the housing. The cap includes a threaded interior surface which movably engages the plunger rod for calibrated adjustment relative thereto. The calibrated adjustment permits one to both increase and decrease the amount of liquid sought to be injected from the pen. A stop is provided within the housing and a distal facing surface is provided on the hollow cap for contacting the stop upon linear movement of the cap and plunger rod as a unit toward the container to dispense liquid therefrom.

The apparatus as a whole is constructed from inexpensive materials and is adapted for machine assembly which contributes directly to a very low manufacturing cost thereby permitting the apparatus as a whole to be disposable. As indicated previously, the adjustment of the dose can be increased and decreased thereby diminishing any waste of the medicating liquid. The dose indication feature is simply and directly read thereby providing for a more accurate and cost effective use of the medicating liquid dispensed from the apparatus. Additional features and advantages will become apparent to those skilled in the art from the following detailed discussion of preferred embodiments exemplifying the best mode of carrying out the invention as presently perceived. The detailed description particularly refers to the accompanying figures.

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is an exploded perspective view of one embodiment of a syringe in accordance with the present invention.

FIG. 2 is a sectional detail view of the syringe shown in FIG. 1 showing the dosage adjustment features.

FIG. 3 is an exploded perspective view of an alternative embodiment for a portion of the hollow cap including a maximum dosage restriction feature.

FIG. 4 is an elevation view of the alternative embodiment shown in FIG. 3 partially assembled.

FIGS. 5–9 are elevation views partially broken away of the embodiment shown in FIG. 4 in five different positions to illustrate the dose restriction features of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A syringe 10 in accordance with the present invention is shown in FIGS. 1 and 2 to include a housing 12 which is adapted to receive a container 14 of liquid within a distal region 15 situated between the distal end 18 and a first shoulder 17. A proximal region 13 between the first shoulder 17 and proximal end 16 is adapted to receive the adjustment apparatus hereinafter described. The proximal region 13 includes a ribbed portion 19 which aids in the calibration and delivery of an accurate dose from the syringe. The distal end 18 of the housing 12 is adapted to receive a needle assembly 20 including a double-ended needle 22 having a distal end 24 which is adapted to permit subcutaneous or intramuscular injection and a proximal end 23 adapted to penetrate the rubber tip cover 26 of container 14. The container 14 is secured within the housing 12 by collar 28 which has an outer diameter providing an interference fit with the inside wall of the proximal portion 13 of housing 12 and forward face 30 intended to abut the proximal end 32 of container 14 adjacent first shoulder 17. The container 14 is shown to generally comprise a cylindrical envelope 34 including a piston 36 initially positioned near the proximal end 32 of the container 14 but movable with respect to the cylindrical wall 34 so as to define a variable liquid-containing volume for the container 14.

After the container 14 is situated within the housing 12 and retained in position by collar 28, the needle assembly 20 can be engaged on the distal end 18 of housing 12 by an appropriate securing means such as threads 38 on an inner surface of the needle assembly 20 engaging threads 40 on an outer distal surface of housing 12. Upon full engagement of the needle assembly 20 to the housing 12, a proximal end 23 of needle 22 penetrates the rubber portion 26 of the end cap 42 of container 14 thereby providing a pathway for liquid within the container 14 to be dispensed through needle 22.

A safety shield 44 including a sheath portion 46 and an engagement portion 48 is frictionally engaged on the needle assembly 20 to safely shield the needle from improper use. A covering element 52 including a clip 54 is used to enclose the distal end of the housing 12, needle assembly 20, and safety shield 44. The clip 54 cooperates with the sidewall of housing 12 to provide a convenient means for holding the syringe 10 in a pocket.

The syringe also includes a plunger rod 56 having a distal end 58 for contacting piston 36 of container 14. The plunger rod 56 has a noncylindrical cross section with a first surface 60 of larger radial dimension which includes threads 62, and a second surface 64 of smaller radial dimension. The plunger rod 56 is received within the non-cylindrical opening 68 of collar 28. The interference relationship between the noncylindrical opening 68 of collar 28 and the noncylindrical cross section of plunger rod 56 prevents rotation of the plunger rod 56 within the housing 12.

An inner surface 70 of collar 28 can include prongs 71 as shown in FIG. 1 which engage and dig into surface 64 of the plunger rod 56 to restrict movement of the plunger rod toward the proximal end 16 of housing 12. The prongs 71 on the inner surfaces 70 of collar 28 permit movement of the plunger rod 56 toward the distal end of the syringe 10 so as to cause the piston 36 to move within container 14 so as to diminish the volume of the container. Alternatively, the second surface 64 can include a line of ratchet teeth 66 as shown in FIG. 2. The ratchet teeth 66 can interact with the inner surfaces 70 of collar 28 even in the absence of prongs to restrict rearward movement of the plunger rod 56.

A hollow two-piece cap 72 is provided which envelopes substantially all of plunger rod 56 including proximal end 50. The cap 72 includes a distal portion 74 and a proximal portion 86 which can be manufactured separately for simplicity. The distal portion 74 comprises a generally cylindrical tube 76 having a threaded inner surface 78 at a distal end 80 thereof. The proximal portion 86 is of slightly greater outside diameter than distal portion 74. A proximal end 82 of distal portion 74 is fixed to a distal end 84 of the proximal portion 86 of cap 72 thereby forming a perimeteral distal end facing surface. A proximal end 88 of the proximal portion 86 protrudes from housing 12 at all times and can include ribs or serrations 90 adapted to permit easy adjustment of the volume to be injected using the syringe 10. The cap 72 includes indicia 92 providing a visual indication of the measured amount of liquid to be injected and includes a radially projecting tang 94 which interacts with a grooved interior 19 of housing 12. The tang 94 functions to provide an audible and tactile indication of the amount or degree of rotational movement of cap 72 with respect to housing 12. The tang 94 also aids linear movement of cap 72 with respect to housing 12 under the application of a force normal to the proximal end 98 of cap 72.

In operation, one desiring to inject a measured amount of liquid would first grasp the housing 12 in one hand and the ribbed portion 90 of cap 72 in the other. One would then rotate cap 72 in a counter-clockwise direction causing the threads 78 of cap 72 to travel along the threaded portion 62 of rod 56. This rotation would not cause displacement of the rod 56 with respect to the housing 12, but would back the distal end 84 of the proximal cap portion 86 away from stop shoulder 48 on the inside of housing 12. The counter-clockwise rotation of the cap 72 would also expose an increasing amount of indicia 92 above the proximal end 16 of the housing 12.

When used in connection with the dispensing of insulin, the indicia 92 is preferably denominated in international units. Other direct calibration scales can be used with other medications so that no computations are necessary to specify the desired dosage to be delivered. The dose scale provided by the indicia 92 is read directly at the end of the proximal end 16 of the housing 12. The dose corresponds to the number corresponding to the last exposed step in the stepped line 93. In order that the indicia 92 can be calibrated in international units or equivalent direct measures of the medication in the container 14, the solutions or suspensions contained in the container 14 are preferably concentrated or diluted to optimize the potency of the medication so as to produce the desired physiological response in coordination with the scale adopted for in indicia 92. In the event that one would turn the cap 72 too far, it can also be rotated clockwise to diminish the dosage to be delivered without effecting any change in position of the rod 56 relative to the housing 12.

When the cap 72 has been positioned to the desired dosage as measured by the indicia 92, the safety shield 44 and cover 52 are removed, and the syringe 10 is positioned for injection. A pressure is applied to end 98 of cap 72 causing it to move linearly toward the distal end 18 of housing 12 until a shoulder defined by a radially exposed portion of distal end 84 contacts stop 48. The movement of the cap 72 causes an identical movement of plunger rod 56 past collar 28, and movement of piston 36 within container 14 so as to dispense the liquid therefrom. The needle 22 can then be withdrawn and the safety shield 44 and cover 52 replaced.

FIG. 3 is a perspective view showing a modified distal portion 100 of cap 72 as well as a follower 104 which is adjustable with respect to the threaded outer surface 106 of the distal cap portion 100 and a barrier element 108 which is secured within an upper portion of housing 12. The distal end 110 of the distal portion 100 has a diameter substantially equivalent to that of distal portion 74 and has internal threads 112 identical with threads 78 of distal portion 74.

During the assembly from the relative position shown in FIG. 4, the follower 104 is threaded on threads 106 of cap distal portion 100. The barrier element 108 is then slipped over the distal cap portion 100, and the plunger rod 56 is inserted within the distal portion 100 sufficiently far to permit engagement between the plunger rod 56 and the collar 28 when the apparatus is fully assembled. The distal end 84 of the proximal portion of the cap 86 is then joined to the proximal end 114 of distal portion 100. The two cap portions 86 and 100 can be bonded by a conventional means such as ultrasonic welding or solvents or the like. The assembly is then pushed inside housing 12 until barrier element 108 is situated at the location 116 shown in phantom. The barrier element 108 is then fixed to housing 12 again using solvents, ultrasonic welding, or other conventional techniques. It will be noted that housing 12 now includes a side opening 118 which was not present in FIG. 2, which side opening provides access to follower 104 so as to permit adjustment of the follower 104 along threads 106.

The operation of the embodiment shown in FIGS. 3 and 4 can best be understood by considering FIGS. 5 through 9. FIG. 5 illustrates a syringe 10 in accordance with the present invention in its initial assembled position. The distal end 58 of the plunger rod 56 is shown projecting slightly beyond collar 28. While the end 58 would normally be seated against a rear surface of a piston 36 as shown in FIG. 2, the container of liquid 14 and piston 36 have been omitted for the sake of clarity in illustrating the motion of plunger rod 56. It will be appreciated that the position of the plunger rod shown in FIG. 5 is substantially identical with that shown in FIG. 2, that is, the plunger rod extends within cap 72 throughout substantially the whole length of the cap.

Comparing FIGS. 5 to FIG. 9, it will be noted that follower 104 has been threaded on threaded portion 106 until contacting the distal end 110 of the distal cap portion 100. Barrier element 108 is fixed within housing 12 so that a distal edge 120 of barrier element 108 is substantially flush with the proximal edge of window 118. The proximal edge 122 of barrier element 108 forms a stop against which the distal end 84 of the proximal portion 86 of cap 72 abuts.

In order to dispense a measured amount of liquid, the serrated portion 88 of cap 72 is grasped and rotated in the direction of arrow cap R from the position shown in FIG. 5 to the position shown in FIG. 6. This rotation has the effect of causing the distal facing surface 84 to move rearward through a distance D. The rotating motion of the cap causes tang 94 to traverse linear markings 96 thereby giving an audible and tactile sensation of the rotation which can be correlated with the number of units of the particular medicament being dispensed. This rearward motion also exposes a greater portion of the indicia 92 which can include numbers also indicative of the dosage being prepared for delivery. As previously indicated with respect to the embodiment shown in FIGS. 1 and 2, if cap 72 has been rotated too far, it can be rotated in the opposite direction to diminish the required dose.

A special feature present in the embodiments shown in FIGS. 3 through 9 which is not present in the embodiment shown in FIGS. 1 and 2 is the presence of follower 104 which can be adjusted to any position along threads 106. The principle function of follower 104 is to set a maximum allowable dose where the syringe is going to be used by persons who may have difficulty remembering the proper dosage, or may have some other physical disability which does not permit them to appreciate fully the meaning of the indicia 92. In such a circumstance, the cap 72 can first be rotated to the desired maximum measured value illustrated as an arbitrary position in FIG. 6. Next, the follower 104 is rotated through distance X from the position shown in FIG. 6 to the position shown in FIG. 7. In this position, the upper edge 124 of follower 104 abuts distall edge 120 of barrier element 108. Preferably the engagement between follower 104 and threads 106 is sufficiently tight such that follower 104 is moved only with some difficulty, or at least, the follower 104 is not likely to move merely under the influence of vibration or the like.

With the follower 104 set in the position shown in FIG. 7, the cap 72 can be rotated back to its original position. This rotation back to the starting position, or zero, will not cause any movement of the plunger rod 56 with respect to the collar 28 and hence no dispensing of liquid will take place. Alternatively, a force can be applied to the proximal end 98, as shown by arrow F. thereby moving the cap 72 and plunger rod 56 from the position shown in FIG. 7 until edge 84 once again contacts edge 122 of barrier element 108 thereby assuming the position shown in FIG. 8. It will be noted that with the force F applied to proximal end 98, the cap 72 and plunger rod 56 have both moved linearly through a distance L which is identical to the distance D shown in FIG. 6. The motion of the plunger rod 56 causes a forward motion of plunger 36 as shown in FIG. 2 to dispense the liquid within container 14 as previously discussed.

The syringe 10 may then be stored in the position shown in FIG. 8 until it is next needed for use. The edges 70 of collar 28 prevent any relative movement between the housing 12 and plunger rod 56 merely due to vibration or shock. When it is necessary to again use the syringe one again rotates cap 72 in the direction R from the position shown in FIG. 8 toward the position shown in FIG. 9. The follower 104 now limits the motion which can take place to something significantly less than that which could have been achieved before the follower 104 was moved from the position shown in FIG. 6. The rotating motion of cap 72 relative to housing 12 does not cause any relative motion between housing 12 and plunger rod 56. It will be appreciated that

while follower 104, set in the position shown in FIGS. 7 through 9, limits the maximum dose which might be delivered, a smaller dose could be delivered if the cap 72 were not rotated to the position where follower 104 abutts barrier element 108.

Although the invention has been described in detail with reference to the illustrated preferred embodiments, variations and modifications exist within the scope and spirit of the invention as described and as defined in the following claims.

What is claimed is:

1. An improved means for adjustment of the dosage of liquid to be injected from a syringe having a housing for receiving a container of liquid, the container of liquid having a closed first end and a piston closing a second end of the container, the housing having a proximal end and a distal end, the distal end being adapted to receive an injection needle assembly for permitting liquid to pass out of the container first end, a plunger rod, having a noncylindrical cross-section with a first surface, including threads, and a second surface, received within the housing for exerting a force on the piston closing the container second end, the improvement comprising:

first means received within the housing adjacent the container second end for preventing rotation of the plunger rod in relation to the housing,

second means engaging a second surface of the plunger rod for restricting movement of the plunger rod toward the housing proximal end,

third means, used to adjust the dosage of liquid to be injected from the syringe, which means rotatably engages a first surface of the plunger rod for calibrated axial movement with respect to the plunger rod and housing toward the housing proximal end without causing rotation of the housing, and

fourth means fixed with respect to the housing for stopping any movement of the third means toward the housing distal end at a fixed position relative to the housing.

2. The improvement of claim 1 wherein the first means comprises a collar received within the housing adjacent the container second end, the collar having a non-cylindrical opening corresponding generally to the cross-section of the plunger rod for preventing rotation of the plunger rod with respect to the housing.

3. The improvement of claim 2 wherein the collar comprises a radial outside surface frictionally engaging an inside surface of the housing, and a distal end surface contacting the container of liquid for maintaining the container in fixed position with respect to the housing.

4. The improvement of claim 2 wherein the second means comprises engaging means included within the collar non-cylindrical opening and engaging a second surface on the plunger rod for restricting movement of the plunger rod toward the housing proximal end.

5. The improvement of claim 4 wherein the engaging means comprises a pair of opposed edges situated on opposite sides of the plunger rod each engaging a second surface on the plunger rod so as to prevent movement of the plunger rod toward the housing proximal end.

6. The improvement of claim 1 wherein the second means comprises engaging means engaging a second surface on the plunger rod for restricting movement of the plunger rod toward the housing proximal end.

7. The improvement of claim 6 wherein the engaging means comprises a pair of opposed edges situated on opposite sides of the plunger rod each engaging a surface on the plunger rod so as to prevent movement of the plunger rod toward the housing proximal end.

8. The improvement of claim 1 wherein the third means comprises a hollow cap enveloping the plunger rod end opposite the container and extending outward from the housing proximal end, the cap having a threaded interior surface rotatably engaging the first threaded surface of the plunger rod for calibrated axial adjustment relative thereto without causing rotation of the housing.

9. The improvement of claim 8 wherein the hollow cap further comprises a flexible member projecting outward from the cap and the housing further comprises a grooved interior surface, said flexible member engaging said grooved interior surface of the housing such that the calibrated relative adjustment causes sensible movement of the flexible member.

10. The improvement of claim 1 wherein the third means comprises a hollow cap enveloping the plunger rod end opposite the container and extending outward from the housing proximal end, the cap rotatably engaging the plunger rod and having a distal end facing surface for contacting a stop fixed with respect to the housing upon movement of the cap and plunger rod toward the housing distal end.

11. The improvement of claim 10 wherein the distal end facing surface comprises the distal end of the cap, and the stop comprises a land within the housing situated to contact the distal end of the cap so that a proximal portion of the cap remains projecting from the proximal end of the housing.

12. A syringe having means for adjustment of the dosage of liquid to be injected comprising:

a housing for receiving a container of liquid, the container of liquid having a closed first end an da piston closing a second end of the container, the housing having a proximal end and a distal end, the distal end being adapted to receive a needle assembly for permitting liquid to pass out of the closed first end of the container,

a plunger rod received within the housing for exerting a force on the piston closing the second end of the container, the plunger rod having a non-cylindrical cross section, a first surface including threads, and a second surface,

a collar received within the housing adjacent the container second end, the collar having a non-cylindrical opening corresponding generally to the cross-section of the plunger rod for preventing rotation of the plunger rod with respect to the housing and engaging means engaging the plunger rod second surface for restricting movement of the plunger rod toward the housing proximal end, and

a hollow cap, used to adjust the dosage of liquid to be injected from the syringe, enveloping the plunger rod end opposite the container and extending outward from the housing proximal end, the cap having a threaded interior surface rotatably engaging the plunger rod first surface portion for calibrated axial adjustment relative thereto, without causing rotation of the housing, and a distal end facing surface for contacting a stop fixed with respect to the housing upon movement of the cap and plunger rod toward the housing distal end.

13. The syringe of claim 12 wherein the collar comprises a radial outside surface frictionally engaging an inside surface of the housing, and a distal end surface